SUBCHAPTER A—GENERAL PROVISIONS

PART 1 [RESERVED]

PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

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AUTHORITY: Sec. 408 of Pub. L. 92–255, 86 Stat. 79, as amended by sec. 303 (a), (b) of Pub L. 93–282, 83 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94–237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94–581, 90 Stat. 2852; sec. 509 of Pub. L. 96–88, 93 Stat. 695; sec. 973(d) of Pub. L. 97–35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98–24, 97 Stat. 182 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290ee–3) and sec. 333 of Pub. L. 91–616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93–282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94–581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L. 98–24, 97 Stat. 181 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290dd–3), as amended by sec. 131 of Pub. L. 102–321, 106 Stat. 368, (42 U.S.C. 290dd–2).

SOURCE: 52 FR 21809, June 9, 1987, unless otherwise noted.

Subpart A—Introduction

§ 2.1 Statutory authority for confidentiality of drug abuse patient records.

The restrictions of these regulations upon the disclosure and use of drug abuse patient records were initially authorized by section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1175). That section as amended was transferred by Pub. L. 98–24 to section 527 of the Public Health Service Act which is codified

at 42 U.S.C. 290ee–3. The amended statutory authority is set forth below:

§ 290EE–3. CONFIDENTIALITY OF PATIENT RECORDS.

(a) *Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) *Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) *Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) *Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) *Armed Forces and Veterans' Administration; interchange of records; report of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or witrhin those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) *Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not nore than $5,000 in the case of each subsequent offense.

(g) *Regulations; interagency consultations; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders*

Except as provided in subsection (h) of this section, the Secretary, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(3) of Pub. L. 94–581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of drug abuse patient records under Title 38 was moved from 21 U.S.C. 1175 to 38 U.S.C. 4134.)

§ 2.2 Statutory authority for confidentiality of alcohol abuse patient records.

The restrictions of these regulations upon the disclosure and use of alcohol

abuse patient records were initially authorized by section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582). The section as amended was transferred by Pub. L. 98–24 to section 523 of the Public Health Service Act which is codified at 42 U.S.C. 290dd–3. The amended statutory authority is set forth below:

§ 290DD–3. CONFIDENTIALITY OF PATIENT RECORDS

(a) *Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) *Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) *Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) *Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) *Armed Forces and Veterans' Administration; interchange of record of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) *Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) *Regulations of Secretary; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders*

Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection(b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(4) of Pub. L. 94–581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of alcohol abuse patient records under Title 38 was moved from 42 U.S.C. 4582 to 38 U.S.C. 4134.)

§ 2.3 Purpose and effect.

(a) *Purpose.* Under the statutory provisions quoted in §§ 2.1 and 2.2, these regulations impose restrictions upon the disclosure and use of alcohol and drug abuse patient records which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program. The regulations specify:

(1) Definitions, applicability, and general restrictions in subpart B (definitions applicable to § 2.34 only appear in that section);

(2) Disclosures which may be made with written patient consent and the form of the written consent in subpart C;

(3) Disclosures which may be made without written patient consent or an authorizing court order in subpart D; and

(4) Disclosures and uses of patient records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders in subpart E.

(b) *Effect.* (1) These regulations prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstances exists under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.

(2) These regulations are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.

(3) Because there is a criminal penalty (a fine—see 42 U.S.C. 290ee–3(f), 42 U.S.C. 290dd–3(f) and 42 CFR 2.4) for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute (see *M. Kraus & Brothers* v. *United States,* 327 U.S. 614, 621–22, 66 S. Ct. 705, 707–08 (1946)).

§ 2.4 Criminal penalty for violation.

Under 42 U.S.C. 290ee–3(f) and 42 U.S.C. 290dd–3(f), any person who violates any provision of those statutes or these regulations shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

§ 2.5 Reports of violations.

(a) The report of any violation of these regulations may be directed to the United States Attorney for the judicial district in which the violation occurs.

(b) The report of any violation of these regulations by a methadone program may be directed to the Regional Offices of the Food and Drug Administration.

Subpart B—General Provisions

§ 2.11 Definitions.

For purposes of these regulations:

Alcohol abuse means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

Drug abuse means the use of a psychoactive substance for other than medicinal purposes which impairs the physical, mental, emotional, or social well-being of the user.

Diagnosis means any reference to an individual's alcohol or drug abuse or to a condition which is identified as having been caused by that abuse which is made for the purpose of treatment or referral for treatment.

Disclose or disclosure means a communication of patient indentifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

Informant means an individual:

(a) Who is a patient or employee of a program or who becomes a patient or employee of a program at the request of a law enforcement agency or official: and

(b) Who at the request of a law enforcement agency or official observes one or more patients or employees of

the program for the purpose of reporting the information obtained to the law enforcement agency or official.

Patient means any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program.

Patient identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.

Person means an individual, partnership, corporation, Federal, State or local government agency, or any other legal entity.

Program means:

(a) An individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(b) An identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(c) Medical personnel or other staff in a general medical care facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers. (See §2.12(e)(1) for examples.)

Program director means:

(a) In the case of a program which is an individual, that individual:

(b) In the case of a program which is an organization, the individual designated as director, managing director, or otherwise vested with authority to act as chief executive of the organization.

Qualified service organization means a person which:

(a) Provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

(b) Has entered into a written agreement with a program under which that person:

(1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the progams, it is fully bound by these regulations; and

(2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

Records means any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.

Third party payer means a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

Treatment means the management and care of a patient suffering from alcohol or drug abuse, a condition which is identified as having been caused by that abuse, or both, in order to reduce or eliminate the adverse effects upon the patient.

Undercover agent means an officer of any Federal, State, or local law enforcement agency who enrolls in or becomes an employee of a program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

[52 FR 21809, June 9, 1987, as amended by 60 FR 22297, May 5, 1995]

§2.12 Applicability.

(a) *General*—(1) *Restrictions on disclosure.* The restrictions on disclosure in

these regulations apply to any information, whether or not recorded, which:

(i) Would identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information, or through verification of such an identification by another person; and

(ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date) for the purpose of treating alcohol or drug abuse, making a diagnosis for that treatment, or making a referral for that treatment.

(2) *Restriction on use.* The restriction on use of information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (42 U.S.C. 290ee–3(c), 42 U.S.C. 290dd–3(c)) applies to any information, whether or not recorded which is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date), for the purpose of treating alcohol or drug abuse, making a diagnosis for the treatment, or making a referral for the treatment.

(b) *Federal assistance.* An alcohol abuse or drug abuse program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (c)(2) of this section relating to the Veterans' Administration and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:

(i) Certification of provider status under the Medicare program;

(ii) Authorization to conduct methadone maintenance treatment (see 21 CFR 291.505); or

(iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of alcohol or drug abuse;

(3) It is supported by funds provided by any department or agency of the United States by being:

(i) A recipient of Federal financial assistance in any form, including financial assistance which does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities; or

(ii) Conducted by a State or local government unit which, through general or special revenue sharing or other forms of assistance, receives Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program; or

(4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(c) *Exceptions*—(1) *Veterans' Administration.* These regulations do not apply to information on alcohol and drug abuse patients maintained in connection with the Veterans' Administration provisions of hospital care, nursing home care, domiciliary care, and medical services under title 38, United States Code. Those records are governed by 38 U.S.C. 4132 and regulations issued under that authority by the Administrator of Veterans' Affairs.

(2) *Armed Forces.* These regulations apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

(i) Any interchange of that information within the Armed Forces; and

(ii) Any interchange of that information between the Armed Forces and

those components of the Veterans Administration furnishing health care to veterans.

(3) *Communication within a program or between a program and an entity having direct administrative control over that program.* The restrictions on disclosure in these regulations do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of alcohol or drug abuse if the communications are

(i) Within a program or

(ii) Between a program and an entity that has direct administrative control over the program.

(4) *Qualified Service Organizations.* The restrictions on disclosure in these regulations do not apply to communications between a program and a qualified service organization of information needed by the organization to provide services to the program.

(5) *Crimes on program premises or against program personnel.* The restrictions on disclosure and use in these regulations do not apply to communications from program personnel to law enforcement officers which—

(i) Are directly related to a patient's commission of a crime on the premises of the program or against program personnel or to a threat to commit such a crime; and

(ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts.

(6) *Reports of suspected child abuse and neglect.* The restrictions on disclosure and use in these regulations do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities. However, the restrictions continue to apply to the original alcohol or drug abuse patient records maintained by the program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

(d) *Applicability to recipients of information*—(1) *Restriction on use of information.* The restriction on the use of any information subject to these regulations to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any person who obtains that information from a federally assisted alcohol or drug abuse program, regardless of the status of the person obtaining the information or of whether the information was obtained in accordance with these regulations. This restriction on use bars, among other things, the introduction of that information as evidence in a criminal proceeding and any other use of the information to investigate or prosecute a patient with respect to a suspected crime. Information obtained by undercover agents or informants (see §2.17) or through patient access (see §2.23) is subject to the restriction on use.

(2) *Restrictions on disclosures—Third party payers, administrative entities, and others.* The restrictions on disclosure in these regulations apply to:

(i) Third party payers with regard to records disclosed to them by federally assisted alcohol or drug abuse programs;

(ii) Entities having direct administrative control over programs with regard to information communicated to them by the program under §2.12(c)(3); and

(iii) Persons who receive patient records directly from a federally assisted alcohol or drug abuse program and who are notified of the restrictions on redisclosure of the records in accordance with §2.32 of these regulations.

(e) *Explanation of applicability*—(1) *Coverage.* These regulations cover any information (including information on referral and intake) about alcohol and drug abuse patients obtained by a program (as the terms ''patient'' and ''program'' are defined in §2.11) if the program is federally assisted in any manner described in §2.12(b). Coverage includes, but is not limited to, those treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as

providing, and provide alcohol or drug abuse diagnosis, treatment, or referral for treatment. However, these regulations would not apply, for example, to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose, unless the primary function of such personnel is the provision of alcohol or drug abuse diagnosis, treatment or referral and they are identified as providing such services or the emergency room has promoted itself to the community as a provider of such services.

(2) *Federal assistance to program required.* If a patient's alcohol or drug abuse diagnosis, treatment, or referral for treatment is not provided by a program which is federally conducted, regulated or supported in a manner which constitutes Federal assistance under §2.12(b), that patient's record is not covered by these regulations. Thus, it is possible for an individual patient to benefit from Federal support and not be covered by the confidentiality regulations because the program in which the patient is enrolled is not federally assisted as defined in §2.12(b). For example, if a Federal court placed an individual in a private for-profit program and made a payment to the program on behalf of that individual, that patient's record would not be covered by these regulations unless the program itself received Federal assistance as defined by §2.12(b).

(3) *Information to which restrictions are applicable.* Whether a restriction is on use or disclosure affects the type of information which may be available. The restrictions on disclosure apply to any information which would identify a patient as an alcohol or drug abuser. The restriction on use of information to bring criminal charges against a patient for a crime applies to any information obtained by the program for the purpose of diagnosis, treatment, or referral for treatment of alcohol or drug abuse. (Note that restrictions on use and disclosure apply to recipients of information under §2.12(d).)

(4) *How type of diagnosis affects coverage.* These regulations cover any record of a diagnosis identifying a patient as an alcohol or drug abuser which is prepared in connection with the treatment or referral for treatment of alcohol or drug abuse. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by these regulations. The following are not covered by these regulations:

(i) Diagnosis which is made solely for the purpose of providing evidence for use by law enforcement authorities; or

(ii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved is not an alcohol or drug abuser (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987, as amended at 60 FR 22297, May 5, 1995]

§ 2.13 Confidentiality restrictions.

(a) *General.* The patient records to which these regulations apply may be disclosed or used only as permitted by these regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority. Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

(b) *Unconditional compliance required.* The restrictions on disclosure and use in these regulations apply whether the holder of the information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement or other official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by these regulations.

(c) *Acknowledging the presence of patients: Responding to requests.* (1) The presence of an identified patient in a facility or component of a facility which is publicly identified as a place where only alcohol or drug abuse diagnosis, treatment, or referral is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of these regulations or if an authorizing court order is entered in accordance with subpart E of these regulations. The regulations permit acknowledgement of the presence of an identified patient in a facility or part of a facility if the

facility is not publicy identified as only an alcohol or drug abuse diagnosis, treatment or referral facility, and if the acknowledgement does not reveal that the patient is an alcohol or drug abuser.

(2) Any answer to a request for a disclosure of patient records which is not permissible under these regulations must be made in a way that will not affirmatively reveal that an identified individual has been, or is being diagnosed or treated for alcohol or drug abuse. An inquiring party may be given a copy of these regulations and advised that they restrict the disclosure of alcohol or drug abuse patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient. The regulations do not restrict a disclosure that an identified individual is not and never has been a patient.

§2.14 Minor patients.

(a) *Definition of minor.* As used in these regulations the term ''minor'' means a person who has not attained the age of majority specified in the applicable State law, or if no age of majority is specified in the applicable State law, the age of eighteen years.

(b) *State law not requiring parental consent to treatment.* If a minor patient acting alone has the legal capacity under the applicable State law to apply for and obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations may be given only by the minor patient. This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement. These regulations do not prohibit a program from refusing to provide treatment until the minor patient consents to the disclosure necessary to obtain reimbursement, but refusal to provide treatment may be prohibited under a State or local law requiring the program to furnish the service irrespective of ability to pay.

(c) *State law requiring parental consent to treatment.* (1) Where State law requires consent of a parent, guardian, or other person for a minor to obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations must be given by both the minor and his or her parent, guardian, or other person authorized under State law to act in the minor's behalf.

(2) Where State law requires parental consent to treatment the fact of a minor's application for treatment may be communicated to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf only if:

(i) The minor has given written consent to the disclosure in accordance with subpart C of these regulations or

(ii) The minor lacks the capacity to make a rational choice regarding such consent as judged by the program director under paragraph (d) of this section.

(d) *Minor applicant for services lacks capacity for rational choice.* Facts relevant to reducing a threat to the life or physical well being of the applicant or any other individual may be disclosed to the parent, guardian, or other person authorized under State law to act in the minor's behalf if the program director judges that:

(1) A minor applicant for services lacks capacity because of extreme youth or mental or physical condition to make a rational decision on whether to consent to a disclosure under subpart C of these regulations to his or her parent, guardian, or other person authorized under State law to act in the minor's behalf, and

(2) The applicant's situation poses a substantial threat to the life or physical well being of the applicant or any other individual which may be reduced by communicating relevant facts to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf.

§2.15 Incompetent and deceased patients.

(a) *Incompetent patients other than minors*—(1) *Adjudication of incompetence.* In the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs, any consent which is required under these regulations may be given by the

guardian or other person authorized under State law to act in the patient's behalf.

(2) *No adjudication of incompetency.* For any period for which the program director determines that a patient, other than a minor or one who has been adjudicated incompetent, suffers from a medical condition that prevents knowing or effective action on his or her own behalf, the program director may exercise the right of the patient to consent to a disclosure under subpart C of these regulations for the sole purpose of obtaining payment for services from a third party payer.

(b) *Deceased patients*—(1) *Vital statistics.* These regulations do not restrict the disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.

(2) *Consent by personal representative.* Any other disclosure of information identifying a deceased patient as an alcohol or drug abuser is subject to these regulations. If a written consent to the disclosure is required, that consent may be given by an executor, administrator, or other personal representative appointed under applicable State law. If there is no such appointment the consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family.

§ 2.16 Security for written records.

(a) Written records which are subject to these regulations must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use; and

(b) Each program shall adopt in writing procedures which regulate and control access to and use of written records which are subject to these regulations.

§ 2.17 Undercover agents and informants.

(a) *Restrictions on placement.* Except as specifically authorized by a court order granted under § 2.67 of these regulations, no program may knowingly employ, or enroll as a patient, any undercover agent or informant.

(b) *Restriction on use of information.* No information obtained by an undercover agent or informant, whether or not that undercover agent or informant is placed in a program pursuant to an authorizing court order, may be used to criminally investigate or prosecute any patient.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.18 Restrictions on the use of identification cards.

No person may require any patient to carry on his or her person while away from the program premises any card or other object which would identify the patient as an alcohol or drug abuser. This section does not prohibit a person from requiring patients to use or carry cards or other identification objects on the premises of a program.

§ 2.19 Disposition of records by discontinued programs.

(a) *General.* If a program discontinues operations or is taken over or acquired by another program, it must purge patient identifying information from its records or destroy the records unless—

(1) The patient who is the subject of the records gives written consent (meeting the requirements of § 2.31) to a transfer of the records to the acquiring program or to any other program designated in the consent (the manner of obtaining this consent must minimize the likelihood of a disclosure of patient identifying information to a third party); or

(2) There is a legal requirement that the records be kept for a period specified by law which does not expire until after the discontinuation or acquisition of the program.

(b) *Procedure where retention period required by law.* If paragraph (a)(2) of this section applies, the records must be:

(1) Sealed in envelopes or other containers labeled as follows: ''Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date]''; and

(2) Held under the restrictions of these regulations by a responsible person who must, as soon as practicable

after the end of the retention period specified on the label, destroy the records.

§ 2.20 Relationship to State laws.

The statutes authorizing these regulations (42 U.S.C. 290ee–3 and 42 U.S.C. 290dd–3) do not preempt the field of law which they cover to the exclusion of all State laws in that field. If a disclosure permitted under these regulations is prohibited under State law, neither these regulations nor the authorizing statutes may be construed to authorize any violation of that State law. However, no State law may either authorize or compel any disclosure prohibited by these regulations.

§ 2.21 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.

(a) *Research privilege description.* There may be concurrent coverage of patient identifying information by these regulations and by administrative action taken under: Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a) and the implementing regulations at 42 CFR part 2a); or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These ''research privilege'' statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) *Effect of concurrent coverage.* These regulations restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under subpart E of these regulations of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes. However, the research privilage granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any imformation which is permitted to be disclosed under those regulations. Thus, if a court order entered in accordance with subpart E of these regulations authorizes a methadone maintenance treatment program to disclose certain information about its patients, that program may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

§ 2.22 Notice to patients of Federal confidentiality requirements.

(a) *Notice required.* At the time of admission or as soon threreafter as the patient is capable of rational communication, each program shall:

(1) Communicate to the patient that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records; and

(2) Give to the patient a summary in writing of the Federal law and regulations.

(b) *Required elements of written summary.* The written summary of the Federal law and regulations must include:

(1) A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser.

(2) A statement that violation of the Federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with these regulations.

(3) A statement that information related to a patient's commission of a crime on the premises of the program or against personnel of the program is not protected.

(4) A statement that reports of suspected child abuse and neglect made under State law to appropriate State or local authorities are not protected.

(5) A citation to the Federal law and regulations.

(c) *Program options.* The program may devise its own notice or may use the

sample notice in paragraph (d) to comply with the requirement to provide the patient with a summary in writing of the Federal law and regulations. In addition, the program may include in the written summary information concerning State law and any program policy not inconsistent with State and Federal law on the subject of confidentiality of alcohol and drug abuse patient records.

(d) *Sample notice.*

CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

The confidentiality of alcohol and drug abuse patient records maintained by this program is protected by Federal law and regulations. Generally, the program may not say to a person outside the program that a patient attends the program, or disclose any information identifying a patient as an alcohol or drug abuser *Unless:*

(1) The patient consents in writing:

(2) The disclosure is allowed by a court order; or

(3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

Violation of the Federal law and regulations by a program is a crime. Suspected violations may be reported to appropriate authorities in accordance with Federal regulations.

Federal law and regulations do not protect any information about a crime committed by a patient either at the program or against any person who works for the program or about any threat to commit such a crime.

Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities.

(See 42 U.S.C. 290dd–3 and 42 U.S.C. 290ee–3 for Federal laws and 42 CFR part 2 for Federal regulations.)

(Approved by the Office of Management and Budget under control number 0930–0099)

§ 2.23 Patient access and restrictions on use.

(a) *Patient access not prohibited.* These regulations do not prohibit a program from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. The program is not required to obtain a patient's written consent or other authorization under these regulations in order to provide such access to the patient.

(b) *Restriction on use of information.* Information obtained by patient access to his or her patient record is subject to the restriction on use of his information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 2.12(d)(1).

Subpart C—Disclosures With Patient's Consent

§ 2.31 Form of written consent.

(a) *Required elements.* A written consent to a disclosure under these regulations must include:

(1) The specific name or general designation of the program or person permitted to make the disclosure.

(2) The name or title of the individual or the name of the organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose of the disclosure.

(5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 2.15 in lieu of the patient.

(7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) *Sample consent form.* The following form complies with paragraph (a) of this section, but other elements may be added.

1. I (name of patient) ☐ Request ☐ Authorize:
2. (name or general designation of program which is to make the disclosure)

_____

3. To disclose: (kind and amount of information to be disclosed)

_____

4. To: (name or title of the person or organization to which disclosure is to be made)

_____

5. For (purpose of the disclosure)

_____

6. Date (on which this consent is signed)

_____

7. Signature of patient

_____

8. Signature of parent or guardian (where required)

_____

9. Signature of person authorized to sign in lieu of the patient (where required)

_____

10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: (specific date, event, or condition)

(c) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

(1) Has expired;

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

(Approved by the Office of Management and Budget under control number 0930–0099)

§ 2.32 Prohibition on redisclosure.

Notice to accompany disclosure. Each disclosure made with the patient's written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

[52 FR 21809, June 9, 1987; 52 FR 41997, Nov. 2, 1987]

§ 2.33 Disclosures permitted with written consent.

If a patient consents to a disclosure of his or her records under § 2.31, a program may disclose those records in accordance with that consent to any individual or organization named in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 2.34 and 2.35, respectively.

§ 2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs.

(a) *Definitions.* For purposes of this section:

Central registry means an organization which obtains from two or more member progams patient identifying information about individuals applying for maintenance treatment or detoxification treatment for the purpose of avoiding an individual's concurrent enrollment in more than one program.

Detoxification treatment means the dispensing of a narcotic drug in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to withdrawal from the sustained use of a narcotic drug.

Maintenance treatment means the dispensing of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

Member program means a detoxification treatment or maintenance treatment program which reports patient identifying information to a central registry and which is in the same State as that central registry or is not more than 125 miles from any border of the State in which the central registry is located.

(b) *Restrictions on disclosure.* A program may disclose patient records to a central registry or to any detoxification or maintenance treatment program not more than 200 miles away for the purpose of preventing the multiple enrollment of a patient only if:

(1) The disclosure is made when:

(i) The patient is accepted for treatment;

(ii) The type or dosage of the drug is changed; or

(iii) The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

(i) Patient identifying information;

(ii) Type and dosage of the drug; and

(iii) Relevant dates.

(3) The disclosure is made with the patient's written consent meeting the requirements of §2.31, except that:

(i) The consent must list the name and address of each central registry and each known detoxification or maintenance treatment program to which a disclosure will be made; and

(ii) The consent may authorize a disclosure to any detoxification or maintenance treatment program established within 200 miles of the program after the consent is given without naming any such program.

(c) *Use of information limited to prevention of multiple enrollments.* A central registry and any detoxification or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not redisclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a court order under subpart E of these regulations.

(d) *Permitted disclosure by a central registry to prevent a multiple enrollment.* When a member program asks a central registry if an identified patient is enrolled in another member program and the registry determines that the patient is so enrolled, the registry may disclose—

(1) The name, address, and telephone number of the member program(s) in which the patient is already enrolled to the inquiring member program; and

(2) The name, address, and telephone number of the inquiring member program to the member program(s) in which the patient is already enrolled. The member programs may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollment.

(e) *Permitted disclosure by a detoxification or maintenance treatment program to prevent a multiple enrollment.* A detoxification or maintenance treatment program which has received a disclosure under this section and has determined that the patient is already enrolled may communicate as necessary with the program making the disclosure to verify that no error has been made and to prevent or eliminate any multiple enrollment.

§ 2.35 Disclosures to elements of the criminal justice system which have referred patients.

(a) A program may disclose information about a patient to those persons within the criminal justice system which have made participation in the program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

(1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or posttrial release, probation or parole officers responsible for supervision of the patient); and

(2) The patient has signed a written consent meeting the requirements of §2.31 (except paragraph (a)(8) which is inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this section.

(b) *Duration of consent.* The written consent must state the period during which it remains in effect. This period must be reasonable, taking into account:

(1) The anticipated length of the treatment;

(2) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when the final disposition will occur; and

(3) Such other factors as the program, the patient, and the person(s) who will receive the disclosure consider pertinent.

(c) *Revocation of consent.* The written consent must state that it is revocable upon the passage of a specified amount of time or the occurrence of a specified,

ascertainable event. The time or occurrence upon which consent becomes revocable may be no later than the final disposition of the conditional release or other action in connection with which consent was given.

(d) *Restrictions on redisclosure and use.* A person who receives patient information under this section may redisclose and use it only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the consent was given.

Subpart D—Disclosures Without Patient Consent

§ 2.51 Medical emergencies.

(a) *General Rule.* Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.

(b) *Special Rule.* Patient identifying information may be disclosed to medical personnel of the Food and Drug Administration (FDA) who assert a reason to believe that the health of any individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction, and that the information will be used for the exclusive purpose of notifying patients or their physicians of potential dangers.

(c) *Procedures.* Immediately following disclosure, the program shall document the disclosure in the patient's records, setting forth in writing:

(1) The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;

(2) The name of the individual making the disclosure;

(3) The date and time of the disclosure; and

(4) The nature of the emergency (or error, if the report was to FDA).

(Approved by the Office of Management and Budget under control number 0930–0099)

§ 2.52 Research activities.

(a) Patient identifying information may be disclosed for the purpose of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:

(1) Is qualified to conduct the research;

(2) Has a research protocol under which the patient identifying information:

(i) Will be maintained in accordance with the security requirements of § 2.16 of these regulations (or more stringent requirements); and

(ii) Will not be redisclosed except as permitted under paragraph (b) of this section; and

(3) Has provided a satisfactory written statement that a group of three or more individuals who are independent of the research project has reviewed the protocol and determined that:

(i) The rights and welfare of patients will be adequately protected; and

(ii) The risks in disclosing patient identifying information are outweighed by the potential benefits of the research.

(b) A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identities.

[52 FR 21809, June 9, 1987, as amended at 52 FR 41997, Nov. 2, 1987]

§ 2.53 Audit and evaluation activities.

(a) *Records not copied or removed.* If patient records are not copied or removed, patient identifying information may be disclosed in the course of a review of records on program premises to any person who agrees in writing to comply with the limitations on redisclosure and use in paragraph (d) of this section and who:

(1) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is

authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third party payer covering patients in the program, or which is a peer review organization performing a utilization or quality control review; or

(2) Is determined by the program director to be qualified to conduct the audit or evaluation activities.

(b) *Copying or removal of records.* Records containing patient identifying information may be copied or removed from program premises by any person who:

(1) Agrees in writing to:

(i) Maintain the patient identifying information in accordance with the security requirements provided in §2.16 of these regulations (or more stringent requirements);

(ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and

(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section; and

(2) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third part payer covering patients in the program, or which is a peer review organization performing a utilization or quality control review.

(c) *Medicare or Medicaid audit or evaluation.* (1) For purposes of Medicare or Medicaid audit or evaluation under this section, audit or evaluation includes a civil or administrative investigation of the program by any Federal, State, or local agency responsible for oversight of the Medicare or Medicaid program and includes administrative enforcement, against the program by the agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.

(2) Consistent with the definition of program in §2.11, program includes an employee of, or provider of medical services under, the program when the employee or provider is the subject of a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section.

(3) If a disclosure to a person is authorized under this section for a Medicare or Medicaid audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section, then a peer review organization which obtains the information under paragraph (a) or (b) may disclose the information to that person but only for purposes of Medicare or Medicaid audit or evaluation.

(4) The provisions of this paragraph do not authorize the agency, the program, or any other person to disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the Medicare or Medicaid audit or evaluation activity as specified in this paragraph.

(d) *Limitations on disclosure and use.* Except as provided in paragraph (c) of this section, patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order entered under §2.66 of these regulations.

Subpart E—Court Orders Authorizing Disclosure and Use

§ 2.61 Legal effect of order.

(a) *Effect.* An order of a court of competent jurisdiction entered under this subpart is a unique kind of court order. Its only purpose is to authorize a disclosure or use of patient information which would otherwise be prohibited by 42 U.S.C. 290ee–3, 42 U.S.C. 290dd–3 and these regulations. Such an order does not compel disclosure. A subpoena or a similar legal mandate must be issued in order to compel disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under these regulations.

(b) *Examples.* (1) A person holding records subject to these regulations receives a subpoena for those records: a response to the subpoena is not permitted under the regulations unless an authorizing court order is entered. The person may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under these regulations.

(2) An authorizing court order is entered under these regulations, but the person authorized does not want to make the disclosure. If there is no subpoena or other compulsory process or a subpoena for the records has expired or been quashed, that person may refuse to make the disclosure. Upon the entry of a valid subpoena or other compulsory process the person authorized to disclose must disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of these regulations.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.

A court order under these regulations may not authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting research, audit or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under § 2.66 may authorize disclosure and use of records to investigate or prosecute qualified personnel holding the records.

§ 2.63 Confidential communications.

(a) A court order under these regulations may authorize disclosure of confidential communications made by a patient to a program in the course of diagnosis, treatment, or referral for treatment only if:

(1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties;

(2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or

(3) The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.

(b) [Reserved]

§ 2.64 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.

(a) *Application.* An order authorizing the disclosure of patient records for purposes other than criminal investigation or prosecution may be applied for by any person having a legally recognized interest in the disclosure which is sought. The application may be filed separately or as part of a pending civil action in which it appears that the patient records are needed to provide evidence. An application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the patient is the applicant or has given a written consent (meeting the requirements of these regulations) to disclosure or the court has ordered the record of the proceeding sealed from public scrunity.

(b) *Notice.* The patient and the person holding the records from whom disclosure is sought must be given:

(1) Adequate notice in a manner which will not disclose patient identifying information to other persons; and

(2) An opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Review of evidence: Conduct of hearing.* Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers or in some manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, or the person holding the record, unless the patient requests an open hearing in a

manner which meets the written consent requirements of these regulations. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria for entry of order.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find that:

(1) Other ways of obtaining the information are not available or would not be effective; and

(2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

(e) *Content of order.* An order authorizing a disclosure must:

(1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those persons whose need for information is the basis for the order; and

(3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

§ 2.65 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.

(a) *Application.* An order authorizing the disclosure or use of patient records to criminally investigate or prosecute a patient may be applied for by the person holding the records or by any person conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws. The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending criminal action. An application must use a fictitious name such as John Doe, to refer to any patient and may not contain or otherwise disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice and hearing.* Unless an order under §2.66 is sought with an order under this section, the person holding the records must be given:

(1) Adequate notice (in a manner which will not disclose patient identifying information to third parties) of an application by a person performing a law enforcement function;

(2) An opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order; and

(3) An opportunity to be represented by counsel independent of counsel for an applicant who is a person performing a law enforcement function.

(c) *Review of evidence: Conduct of hearings.* Any oral argument, review of evidence, or hearing on the application shall be held in the judge's chambers or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient, or the person holding the records. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria.* A court may authorize the disclosure and use of patient records for the purpose of conducting a criminal investigation or prosecution of a patient only if the court finds that all of the following criteria are met:

(1) The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.

(2) There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.

(3) Other ways of obtaining the information are not available or would not be effective.

(4) The potential injury to the patient, to the physician-patient relationship and to the ability of the program to provide services to other patients is outweighed by the public interest and the need for the disclosure.

(5) If the applicant is a person performing a law enforcement function that:

(i) The person holding the records has been afforded the opportunity to be

represented by independent counsel; and

(ii) Any person holding the records which is an entity within Federal, State, or local government has in fact been represented by counsel independent of the applicant.

(e) *Content of order.* Any order authorizing a disclosure or use of patient records under this section must:

(1) Limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of extremely serious crime or suspected crime specified in the application; and

(3) Include such other measures as are necessary to limit disclosure and use to the fulfillment of only that public interest and need found by the court.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records.

(a) *Application.* (1) An order authorizing the disclosure or use of patient records to criminally or administratively investigate or prosecute a program or the person holding the records (or employees or agents of that program or person) may be applied for by any administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the program's or person's activities.

(2) The application may be filed separately or as part of a pending civil or criminal action against a program or the person holding the records (or agents or employees of the program or person) in which it appears that the patient records are needed to provide material evidence. The application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny or the patient has given a written consent (meeting the requirements of § 2.31 of these regulations) to that disclosure.

(b) *Notice not required.* An application under this section may, in the discretion of the court, be granted without notice. Although no express notice is required to the program, to the person holding the records, or to any patient whose records are to be disclosed, upon implementation of an order so granted any of the above persons must be afforded an opportunity to seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Requirements for order.* An order under this section must be entered in accordance with, and comply with the requirements of, paragraphs (d) and (e) of § 2.64 of these regulations.

(d) *Limitations on disclosure and use of patient identifying information:* (1) An order entered under this section must require the deletion of patient identifying information from any documents made available to the public.

(2) No information obtained under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under § 2.65 of these regulations.

§ 2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.

(a) *Application.* A court order authorizing the placement of an undercover agent or informant in a program as an employee or patient may be applied for by any law enforcement or prosecutorial agency which has reason to believe that employees or agents of the program are engaged in criminal misconduct.

(b) *Notice.* The program director must be given adequate notice of the application and an opportunity to appear and be heard (for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order), unless the application asserts a belief that:

(1) The program director is involved in the criminal activities to be investigated by the undercover agent or informant; or

(2) The program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.

(c) *Criteria.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find:

(1) There is reason to believe that an employee or agent of the program is engaged in criminal activity;

(2) Other ways of obtaining evidence of this criminal activity are not available or would not be effective; and

(3) The public interest and need for the placement of an undercover agent or informant in the program outweigh the potential injury to patients of the program, physician-patient relationships and the treatment services.

(d) *Content of order.* An order authorizing the placement of an undercover agent or informant in a program must:

(1) Specifically authorize the placement of an undercover agent or an informant;

(2) Limit the total period of the placement to six months;

(3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to criminally investigate or prosecute employees or agents of the program; and

(4) Include any other measures which are appropriate to limit any potential disruption of the program by the placement and any potential for a real or apparent breach of patient confidentiality; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

(e) *Limitation on use of information.* No information obtained by an undercover agent or informant placed under this section may be used to criminally investigate or prosecute any patient or as the basis for an application for an order under §2.65 of these regulations.

PART 2a—PROTECTION OF IDENTITY—RESEARCH SUBJECTS

Sec.

AUTHORITY: Sec. 3(a), Pub. L. 91–513 as amended by sec. 122(b), Pub. L. 93–282; 84 Stat. 1241 (42 U.S.C. 242a(a)), as amended by 88 Stat. 132.

SOURCE: 44 FR 20384, Apr. 4, 1979, unless otherwise noted.

§2a.1 Applicability.

(a) Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) provides that ''[t]he Secretary [of Health and Human Services] may authorize persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.'' The regulations in this part establish procedures under which any person engaged in research on mental health including research on the use and effect of alcohol and other psychoactive drugs (whether or not the research is federally funded) may, subject to the exceptions set forth in paragraph (b) of this section, apply for such an authorization of confidentiality.

(b) These regulations do not apply to:

(1) Authorizations of confidentiality for research requiring an Investigational New Drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or to approved new drugs, such as methadone, requiring continuation of long-

term studies, records, and reports. Attention is called to 21 CFR 291.505(g) relating to authorizations of confidentiality for patient records maintained by methadone treatment programs.

(2) Authorizations of confidentiality for research which are related to law enforcement activities or otherwise within the purview of the Attorney General's authority to issue authorizations of confidentiality pursuant to section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)) and 21 CFR 1316.21.

(c) The Secretary's regulations on confidentiality of alcohol and drug abuse patient records (42 CFR part 2) and the regulations of this part may, in some instances, concurrently cover the same transaction. As explained in 42 CFR 2.24 and 2.24–1, 42 CFR part 2 restricts voluntary disclosures of information from applicable patient records while a Confidentiality Certificate issued pursuant to the regulations of this part protects a person engaged in applicable research from being compelled to disclose identifying characteristics of individuals who are the subject of such research.

§ 2a.2 Definitions.

(a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(b) *Person* means any individual, corporation, government, or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(c) *Research* means systematic study directed toward new or fuller knowledge and understanding of the subject studied. The term includes, but is not limited to, behavioral science studies, surveys, evaluations, and clinical investigations.

(d) *Drug* has the meaning given that term by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

(e) *Controlled drug* means a drug which is included in schedule I, II, III, IV, or V of part B of the Controlled Substances Act (21 U.S.C. 811–812).

(f) *Administer* refers to the direct application of a drug to the body of a human research subject, whether such application be by injection, inhalation, ingestion, or any other means, by (1) a qualified person engaged in research (or, in his or her presence, by his or her authorized agent), or (2) a research subject in accordance with instructions of a qualified person engaged in research, whether or not in the presence of a qualified person engaged in research.

(g) *Identifying characteristics* refers to the name, address, any identifying number, fingerprints, voiceprints, photographs or any other item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of that research subject.

(h) *Psychoactive drug* means, in addition to alcohol, any drug which has as its principal action an effect on thought, mood, or behavior.

§ 2a.3 Application; coordination.

(a) Any person engaged in (or who intends to engage in) the research to which this part applies, who desires authorization to withhold the names and other identifying characteristics of individuals who are the subject of such research from any person or authority not connected with the conduct of such research may apply to the Office of the Director, National Institute on Drug Abuse, the Office of the Director, National Institute of Mental Health, or the Office of the Director, National Institute on Alcohol Abuse and Alcoholism, 5600 Fishers Lane, Rockville, Maryland 20857 for an authorization of confidentiality.

(b) If there is uncertainty with regard to which Institute is appropriate or if the research project falls within the purview of more than one Institute, an application need be submitted only to one Institute. Persons who are uncertain with regard to the applicability of these regulations to a particular type of research may apply for an authorization of confidentiality under the regulations of this part to one of the Institutes. Requests which are within the scope of the authorities described

in §2a.1(b) will be forwarded to the appropriate agency for consideration and the person will be advised accordingly.

(c) An application may accompany, precede, or follow the sumission of a request for DHHS grant or contract assistance, though it is not necessary to request DHHS grant or contract assistance in order to apply for a Confidentiality Certificate. If a person has previously submitted any information required in this part in connection with a DHHS grant or contract, he or she may substitute a copy of information thus submitted, if the information is current and accurate. If a person requests a Confidentiality Certificate at the same time he or she submits an application for DHHS grant or contract assistance, the application for a Confidentiality Certificate may refer to the pertinent section(s) of the DHHS grant or contract application which provide(s) the information required to be submitted under this part. (See §§2a.4 and 2a.5.)

(d) A separate application is required for each research project for which an authorization of confidentiality is requested.

§2a.4 Contents of application; in general.

In addition to any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project shall contain:

(a) The name and address of the individual primarily responsible for the conduct of the research and the sponsor or institution with which he or she is affiliated, if any. Any application from a person affiliated with an institution will be considered only if it contains or is accompanied by documentation of institutional approval. This documentation may consist of a written statement signed by a responsible official of the institution or of a copy of or reference to a valid certification submitted in accordance with 45 CFR part 46.

(b) The location of the research project and a description of the facilities available for conducting the research, including the name and address of any hospital, institution, or clinical laboratory facility to be utilized in connection with the research.

(c) The names, addresses, and summaries of the scientific or other appropriate training and experience of all personnel having major responsibilities in the research project and the training and experience requirements for major positions not yet filled.

(d) An outline of the research protocol for the project including a clear and concise statement of the purpose and rationale of the research project and the general research methods to be used.

(e) The date on which research will begin or has begun and the estimated date for completion of the project.

(f) A specific request, signed by the individual primarily responsible for the conduct of the research, for authority to withhold the names and other identifying characteristics of the research subjects and the reasons supporting such request.

(g) An assurance (1) From persons making application for a Confidentiality Certificate for a research project for which DHHS grant or contract support is received or sought that they will comply with all the requirements of 45 CFR part 46, ''Protection of Human Subjects,'' or

(2) From all other persons making application that they will comply with the informed consent requirements of 45 CFR 46.103(c) and document legally effective informed consent in a manner consistent with the principles stated in 45 CFR 46.110, if it is determined by the Secretary, on the basis of information submitted by the person making application, that subjects will be placed at risk. If a modification of paragraphs (a) or (b) of 45 CFR 46.110 is to be used, as permitted under paragraph (c) of that section, the applicant will describe the proposed modification and submit it for approval by the Secretary.

(h) An assurance that if an authorization of confidentiality is given it will not be represented as an endorsement of the research project by the Secretary or used to coerce individuals to participate in the research project.

(i) An assurance that any person who is authorized by the Secretary to protect the privacy of research subjects

will use that authority to refuse to disclose identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects.

(j) An assurance that all research subjects who participate in the project during the period the Confidentiality Certificate is in effect will be informed that:

(1) A Confidentiality Certificate has been issued;

(2) The persons authorized by the Confidentiality Certificate to protect the identity of research subjects may not be compelled to identify research subjects in any civil, criminal, administrative, legislative, or other proceedings whether Federal, State, or local;

(3) If any of the following conditions exist the Confidentiality Certificate does not authorize any person to which it applies to refuse to reveal identifying information concerning research subjects:

(i) The subject consents in writing to disclosure of identifying information,

(ii) Release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or regulations promulgated thereunder (title 21, Code of Federal Regulations), or

(iii) Authorized personnel of DHHS request identifying information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See §2a.7(b));

(4) The Confidentiality Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects;

(5) The Confidentiality Certificate does not represent an endorsement of the research project by the Secretary.

(k) An assurance that all research subjects who enter the project after the termination of the Confidentiality Certificate will be informed that the authorization of confidentiality has ended and that the persons authorized to protect the identity of research subjects by the Confidentiality Certificate may not rely on the Certificate to refuse to disclose identifying characteristics of research subjects who were not participants in the project during the period the Certificate was in effect. (See §2a.8(c)).

§2a.5 Contents of application; research projects in which drugs will be administered.

(a) In addition to the information required by §2a.4 and any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project which involves the administering of a drug shall contain:

(1) Identification of the drugs to be administered in the research project and a description of the methods for such administration, which shall include a statement of the dosages to be administered to the research subjects;

(2) Evidence that individuals who administer drugs are authorized to do so under applicable Federal and State law; and

(3) In the case of a controlled drug, a copy of the Drug Enforcement Administration Certificate of Registration (BND Form 223) under which the research project will be conducted.

(b) An application for an authorization of confidentiality with respect to a research project which involves the administering of a controlled drug may include a request for exemption of persons engaged in the research from State or Federal prosecution for possession, distribution, and dispensing of controlled drugs as authorized under section 502(d) of the Controlled Substances Act (21 U.S.C. 872(d)) and 21 CFR 1316.22. If the request is in such form, and is supported by such information, as is required by 21 CFR 1316.22, the Secretary will forward it, together with his or her recommendation that such request be approved or disapproved, for the consideration of the Administrator of the Drug Enforcement Administration.

§2a.6 Issuance of Confidentiality Certificates; single project limitation.

(a) In reviewing the information provided in the application for a Confidentiality Certificate, the Secretary will take into account:

(1) The scientific or other appropriate training and experience of all personnel having major responsibilities in the research project;

(2) Whether the project constitutes bona fide ''research'' which is within the scope of the regulations of this part; and

(3) Such other factors as he or she may consider necessary and appropriate. All applications for Confidentiality Certificates shall be evaluated by the Secretary through such officers and employees of the Department and such experts or consultants engaged for this purpose as he or she determines to be appropriate.

(b) After consideration and evaluation of an application for an authorization of confidentiality, the Secretary will either issue a Confidentiality Certificate or a letter denying a Confidentiality Certificate, which will set forth the reasons for such denial, or will request additional information from the person making application. The Confidentiality Certificate will include:

(1) The name and address of the person making application;

(2) The name and address of the individual primarily responsible for conducting the research, if such individual is not the person making application;

(3) The location of the research project;

(4) A brief description of the research project;

(5) A statement that the Certificate does not represent an endorsement of the research project by the Secretary;

(6) The Drug Enforcement Administration registration number for the project, if any; and

(7) The date or event upon which the Confidentiality Certificate becomes effective, which shall not be before the later of either the commencement of the research project or the date of issuance of the Certificate, and the date or event upon which the Certificate will expire.

(c) A Confidentiality Certificate is not transferable and is effective only with respect to the names and other identifying characteristics of those individuals who are the subjects of the single research project specified in the Confidentiality Certificate. The recipient of a Confidentiality Certificate shall, within 15 days of any completion or discontinuance of the research project which occurs prior to the expiration date set forth in the Certificate, provide written notification to the Director of the Institute to which application was made. If the recipient determines that the research project will not be completed by the expiration date set forth in the Confidentiality Certificate he or she may submit a written request for an extension of the expiration date which shall include a justification for such extension and a revised estimate of the date for completion of the project. Upon approval of such a request, the Secretary will issue an amended Confidentiality Certificate.

(d) The protection afforded by a Confidentiality Certificate does not extend to significant changes in the research project as it is described in the application for such Certificate (e.g., changes in the personnel having major responsibilities in the research project, major changes in the scope or direction of the research protocol, or changes in the drugs to be administered and the persons who will administer them). The recipient of a Confidentiality Certificate shall notify the Director of the Institute to which application was made of any proposal for such a significant change by submitting an amended application for a Confidentiality Certificate in the same form and manner as an original application. On the basis of such application and other pertinent information the Secretary will either:

(1) Approve the amended application and issue an amended Confidentiality Certificate together with a Notice of Cancellation terminating original the Confidentiality Certificate in accordance with § 2a.8; or

(2) Disapprove the amended application and notify the applicant in writing that adoption of the proposed significant changes will result in the issuance of a Notice of Cancellation terminating the original Confidentiality Certificate in accordance with § 2a.8.

§ 2a.7 Effect of Confidentiality Certificate.

(a) A Confidentiality Certificate authorizes the withholding of the names and other identifying characteristics of

individuals who participate as subjects in the research project specified in the Certificate while the Certificate is in effect. The authorization applies to all persons who, in the performance of their duties in connection with the research project, have access to information which would identify the subjects of the research. Persons so authorized may not, at any time, be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify the research subjects encompassed by the Certificate, except in those circumstances specified in paragraph (b) of this section.

(b) A Confidentiality Certificate granted under this part does not authorize any person to refuse to reveal the name or other identifying characteristics of any research subject in the following circumstances:

(1) The subject (or, if he or she is legally incompetent, his or her guardian) consents, in writing, to the disclosure of such information,

(2) Authorized personnel of DHHS request such information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See 45 CFR 5.71 for confidentiality standards imposed on such DHHS personnel), or

(3) Release of such information is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or the regulations promulgated thereunder (title 21, Code of Federal Regulations).

(c) Neither a Confidentiality Certificate nor the regulations of this part govern the voluntary disclosure of identifying characteristics of research subjects.

§2a.8 Termination.

(a) A Confidentiality Certificate is in effect from the date of its issuance until the effective date of its termination. The effective date of termination shall be the earlier of:

(1) The expiration date set forth in the Confidentiality Certificate; or

(2) Ten days from the date of mailing a Notice of Cancellation to the applicant, pursuant to a determination by the Secretary that the research project has been completed or discontinued or that retention of the Confidentiality Certificate is otherwise no longer necessary or desirable.

(b) A Notice of Cancellation shall include: an identification of the Confidentiality Certificate to which it applies; the effective date of its termination; and the grounds for cancellation. Upon receipt of a Notice of Cancellation the applicant shall return the Confidentiality Certificate to the Secretary.

(c) Any termination of a Confidentiality Certificate pursuant to this section is operative only with respect to the names and other identifying characteristics of individuals who begin their participation as research subjects after the effective date of such termination. (See §2a.4(k) requiring researchers to notify subjects who enter the project after the termination of the Confidentiality Certificate of termination of the Certificate). The protection afforded by a Confidentiality Certificate is permanent with respect to subjects who participated in research during any time the authorization was in effect.

PART 3 [RESERVED]

PART 4—NATIONAL LIBRARY OF MEDICINE

Sec.

AUTHORITY: 42 U.S.C. 216, 286.

SOURCE: 56 FR 29188, June 26, 1991, unless otherwise noted.

§4.1 Programs to which these regulations apply.

(a) The regulations of this part govern access to the National Library of Medicine's facilities and library collections and the availability of its bibliographic, reproduction, reference, and

related services. These functions are performed by the Library directly for the benefit of the general public and health-sciences professionals as required by sections 465(b) (3)–(6) of the Act (42 U.S.C. 286(b) (3)–(6)).

(b) The regulations of this part do not apply to:

(1) The Library's internal functions relating to the acquisition and preservation of materials and the organization of these materials as required by sections 465(b) (1) and (2) of the Act (42 U.S.C. 286(b) (1) and (2)).

(2) The availability of ''records'' under the Freedom of Information Act or the Privacy Act of 1974 (5 U.S.C. 552, 552a). These matters are covered in 45 CFR parts 5 and 5b.

(3) Federal assistance for medical libraries and other purposes which are authorized by sections 469–477 of the Act (42 U.S.C. 286b to 286b–8). (See parts 59a, 61 and 64 of this chapter.)

(4) The availability of facilities, collections, and related services of Regional Medical Libraries established or maintained under the authority in section 475 of the Act (42 U.S.C. 286b–6). (See part 59a, subpart B of this chapter.)

§ 4.2 Definitions.

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

Collections means all books, periodicals, prints, audiovisual materials, films, videotapes, recordings, manuscripts, and other resource materials of the library. It does not include data processing tapes or programs used solely for internal processing activities to generate reference materials, nor does it include ''records'' of the Library as defined in 45 CFR 5.5. Records of the Library are available in accordance with the regulations under the Freedom of Information Act and Privacy Act of 1974. (See 45 CFR parts 5 and 5b.)

Director means the Director of the National Library of Medicine or the Director's delegate.

Health-sciences professional means any person engaged in: (1) The administration of health activities; (2) the provision of health services; or (3) research, teaching, or education concerned with the advancement of medicine or other sciences related to health or improvement of the public health.

Historical collection means: (1) Materials in the collections published or printed prior to 1914; (2) manuscripts and prints; (3) the archival film collection; and (4) other materials of the collections which, because of age, or unique or unusual value, require special handling, storage, or protection for their preservation, as determined by the Director.

Library means the National Library of Medicine, established by section 465 of the Act (42 U.S.C. 286).

Regional Medical Library means a medical library established or maintained as a regional medical library under section 475 of the Act (42 U.S.C. 286b–6).

§ 4.3 Purpose of the Library.

The purpose of the Library is to assist the advancement of medical and related sciences and aid the dissemination and exchange of scientific and other information important to the progress of medicine and the public health. The Library acquires and maintains library materials pertinent to medicine, including audiovisual materials; compiles, publishes, and disseminates catalogs, indices, and bibliographies of these materials, as appropriate; makes available materials, through loan or otherwise; provides reference and other assistance to research; and engages in other activities in furtherance of this purpose.

§ 4.4 Use of Library facilities.

(a) *General.* The Library facilities are available to any person seeking to make use of the collections. The Director may prescribe reasonable rules to assure the most effective use of facilities by health-sciences professionals and to protect the collections from misuse or damage. These rules must be consistent with the regulations in this part and applicable Department regulations and policies on nondiscrimination.

(b) *Reading rooms.* Public reading rooms are available for obtaining and reading materials from the collections. The Director may prescribe reasonable rules designed to provide adequate

reading space and orderly conditions and procedures.

(c) *Study rooms.* Upon request a limited number of study rooms may be made available to individuals requiring extensive use of Library materials. Requests for study rooms shall be addressed in writing to the Director. The Director shall give priority, in the following order, for study room use to:

(1) Persons engaged in ''special scientific projects'' under section 473 of the Act (42 U.S.C. 286b–4),

(2) Health-sciences professionals, and

(3) The general public.

§4.5 Use of materials from the collections.

(a) *Unrestricted materials.* Except as otherwise provided in this section, materials from the collections are generally available to any interested person only in facilities provided by the Library for this purpose. The Director may prescribe additional reasonable rules to assure the most effective use of the Library's resources by health-sciences professionals and to protect the collections from misuse or damage. The rules must be consistent with the regulations in this part and applicable Department regulations and policies on nondiscrimination. Materials in the collections are available upon each request which assures, to the Director's satisfaction, that the materials will be safeguarded from misuse, damage, loss, or misappropriation, and will be returned promptly after use or upon request of the Library.

(b) *Restricted materials*—(1) *Historical collection.* Materials from the historical collection are available only as the Director may permit to assure their maximum preservation and protection. Copies of these materials may be made available in the form of microfilm and other copies, for which reasonable fees may be charged.

(2) *Gifts.* Materials in the collections are available only in accordance with any limitations imposed as a condition of the acquisition of those materials, whether the acquisition was by gift or purchase.

(c) *Loans*—(1) *General.* Requests for loans of materials must assure the Library that (i) the materials will be safeguarded from misuse, damage, loss, or misappropriation and (ii) the materials will be returned promptly after use or upon request of the Library. The Library may provide copies in lieu of original materials, which need not be returned unless otherwise stated at the time of the loan.

(2) *Loans of audiovisual materials.* Audiovisual materials are available for loan under the same general terms as printed materials.

(3) *Loans to other libraries.* Upon request materials or copies are available for use through libraries of public or private agencies or institutions. The requesting library must assure that it has first exhausted its own collection resources, those of other local libraries in the geographic area, and those of the Regional Medical Library network (including Regional and Resource Libraries) before making a request for a loan.

(4) *Loans to health-sciences professionals.* The Director may make loans of materials directly to health-sciences professionals. An individual wishing a loan of library materials must assure to the satisfaction of the Director that the individual is geographically isolated, in terms of distance or available transportation, from medical literature resources likely to contain the desired material.

(Approved by the Office of Management and Budget under control number 0925–0276)

§4.6 Reference, bibliographic, reproduction, and consultation services.

(a) *General.* To the extent resources permit, the Library will make available, upon request, reference, bibliographic, reproduction, and consultation services. Priority will be given to requests from health-sciences professionals for services not reasonably available through local or regional libraries.

(b) *Specialized bibliographic services.* The Director may provide bibliographies on individually selected medical or scientific topics upon request where it is consistent with the Library's purpose. The Director may publish and make available for general distribution by the Library, bibliographic searches determined to be of general interest. The Library may also produce

and distribute a limited number of bibliographies on topics of general interest to public or nonprofit health-related professional societies, research organizations, and other group users. These bibliographies may be produced on a regularly recurring or intermittent basis under contract between the Library and public or nonprofit agencies, when determined in each case by the Director to be necessary to assure more effective distribution of the bibliographic information.

(c) *Information retrieval system computer tapes.* To the extent Library resources permit and in order to further the Library's purpose, the Director may make available upon request by agencies, organizations, and institutions copies of all or part of the Library's magnetic tapes.

§ 4.7 Fees.

The Director may charge reasonable fees for any service provided by the Library under this part, in accordance with a schedule available at the Library upon request, which are designed to recover all or a portion of the cost to the Library of providing the service.

§ 4.8 Publication of the Library and information about the Library.

Lists of bibliographies, Library publications sold by the Government Printing Office, necessary application forms, and other information concerning the organization, operation, functions, and services of the Library, are available from the National Library of Medicine, Bethesda, Maryland 20894.

PART 5—DESIGNATION OF HEALTH PROFESSIONAL(S) SHORTAGE AREAS

Sec.

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); sec. 332 of the Public Health Service Act, 90 Stat. 2270–2272 (42 U.S.C. 254e).

SOURCE: 45 FR 76000, Nov. 17, 1980, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 5 appear at 57 FR 2480, Jan. 22, 1992.

§ 5.1 Purpose.

These regulations establish criteria and procedures for the designation of geographic areas, population groups, medical facilities, and other public facilities, in the States, as health professional(s) shortage areas.

§ 5.2 Definitions.

Act means the Public Health Service Act, as amended.

Health professional(s) shortage area means any of the following which the Secretary determines has a shortage of health professional(s): (1) An urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services); (2) a population group; or (3) a public or nonprofit private medical facility.

Health service area means a health service area whose boundaries have been designated by the Secretary, under section 1511 of the Act, for purposes of health planning activities.

Health systems agency or *HSA* means the health systems agency designated, under section 1515 of the Act, to carry out health planning activities for a specific health service area.

Medical facility means a facility for the delivery of health services and includes: (1) A community health center,

public health center, outpatient medical facility, or community mental health center; (2) a hospital, State mental hospital, facility for long-term care, or rehabilitation facility; (3) a migrant health center or an Indian Health service facility; (4) a facility for delivery of health services to inmates in a U.S. penal or correctional institution (under section 323 of the Act) or a State correctional institution; (5) a Public Health Service medical facility (used in connection with the delivery of health services under section 320, 321, 322, 324, 325, or 326 of the Act); or (6) any other Federal medical facility.

Metropolitan area means an area which has been designated by the Office of Management and Budget as a standard metropolitan statistical area (SMSA). All other areas are ''non-metropolitan areas.''

Poverty level means the povery level as defined by the Bureau of the Census, using the poverty index adopted by a Federal Interagency Committee in 1969, and updated each year to reflect changes in the Consumer Price Index.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department to whom the authority involved has been delegated.

State includes, in addition to the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

State health planning and development agency or *SHPDA* means a State health planning and development agency designated under section 1521 of the Act.

§ 5.3 Procedures for designation of health professional(s) shortage areas.

(a) Using data available to the Department from national, State, and local sources and based upon the criteria in the appendices to this part, the Department will annually prepare listings (by State and health service area) of currently designated health professional(s) shortage areas and potentially designatable areas, together with appropriate related data available to the Department. Relevant portions of this material will then be forwarded to each health systems agency, State health planning and development agency, and Governor, who will be asked to review the listings for their State, correct any errors of which they are aware, and offer their recommendations, if any, within 90 days, as to which geographic areas, population groups, and facilities in areas under their jurisdiction should be designated. An information copy of these listings will also be made available, upon request, to interested parties for their use in providing comments or recommendations to the Secretary and/or to the appropriate HSA, SHPDA, or Governor.

(b) In addition, any agency or individual may request the Secretary to designate (or withdraw the designation of) a particular geographic area, population group, or facility as a health professional(s) shortage area. Each request will be forwarded by the Secretary to the appropriate HSA, SHPDA, and Governor, who will be asked to review it and offer their recommendations, if any, within 30 days. An information copy will also be made available to other interested parties, upon request, for their use in providing comments or recommendations to the Secretary and/or to the appropriate HSA, SHPDA, or Governor.

(c) In each case where the designation of a public facility (including a Federal medical facility) is under consideration, the Secretary will give written notice of the proposed designation to the chief administrative officer of the facility, who will be asked to review it and offer their recommendations, if any, within 30 days.

(d) After review of the available information and consideration of the comments and recommendations submitted, the Secretary will designate health professional(s) shortage areas and withdraw the designation of any areas which have been determined no longer to have a shortage of health professional(s).

§ 5.4 Notification and publication of designations and withdrawals.

(a) The Secretary will give written notice of the designation (or withdrawal of designation) of a health professional(s) shortage area, not later

than 60 days from the date of the designation (or withdrawal of designation), to:

(1) The Governor of each State in which the area, population group, medical facility, or other public facility so designated is in whole or in part located;

(2) Each HSA for a health service area which includes all or any part of the area, population group, medical facility, or other public facility so designated;

(3) The SHPDA for each State in which the area, population group, medical facility, or other public facility so designated is in whole or in part located; and

(4) Appropriate public or nonprofit private entities which are located in or which have a demonstrated interest in the area so designated.

(b) The Secretary will periodically publish updated lists of designated health professional(s) shortage areas in the FEDERAL REGISTER, by type of professional(s) shortage. An updated list of areas for each type of professional(s) shortage will be published at least once annually.

(c) The effective date of the designation of an area shall be the date of the notification letter to the individual or agency which requested the designation, or the date of publication in the FEDERAL REGISTER, whichever comes first.

(d) Once an area is listed in the FEDERAL REGISTER as a designated health professional(s) shortage area, the effective date of any later withdrawal of the area's designation shall be the date when notification of the withdrawal, or an updated list of designated areas which does not include it, is published in the FEDERAL REGISTER.

APPENDIX A TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PRIMARY MEDICAL CARE PROFESSIONAL(S)

Part I—Geographic Areas

A. *Federal and State Correctional Institutions.*

1. *Criteria.*

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as having a shortage of primary medical care professional(s) if both the following criteria are met:

(a) The institution has at least 250 inmates.

(b) The ratio of the number of internees per year to the number of FTE primary care physicians serving the institution is at least 1,000:1.

Here the number of internees is defined as follows:

(i) If the number of new inmates per year and the average length-of-stay are not specified, or if the information provided does not indicate that intake medical examinations are routinely performed upon entry, then—Number of internees=average number of inmates.

(ii) If the average length-of-stay is specified as one year or more, and intake medical examinations are routinely performed upon entry, then—Number of internees=average number of inmates+(0.3)×number of new inmates per year.

(iii) If the average length-of-stay is specified as less than one year, and intake examinations are routinely performed upon entry, then—Number of internees=average number of inmates+(0.2)×(1+ALOS/2)×number of new inmates per year where ALOS=average length-of-stay (in fraction of year). (The number of FTE primary care physicians is computed as in part I, section B, paragraph 3 above.)

2. Determination of Degree of Shortage.

Designated correctional institutions will be assigned to degree-of-shortage groups based on the number of inmates and/or the ratio (R) of internees to primary care physicians, as follows:

Group 1—Institutions with 500 or more inmates and no physicians.

Group 2—Other institutions with no physicians and institutions with R greater than (or equal to) 2,000:1.

Group 3—Institutions with R greater than (or equal to) 1,000:1 but less than 2,000:1.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

1. *Rational Areas for the Delivery of Primary Medical Care Services.*

(a) The following areas will be considered rational areas for the delivery of primary medical care services:

(i) A county, or a group of contiguous counties whose population centers are within 30 minutes travel time of each other.

(ii) A portion of a county, or an area made up of portions of more than one county, whose population, because of topography, market or transportation patterns, distinctive population characteristics or other factors, has limited access to contiguous area resources, as measured generally by a travel time greater than 30 minutes to such resources.

(iii) Established neighborhoods and communities within metropolitan areas which display a strong self-identity (as indicated by a homogeneous socioeconomic or demographic structure and/or a tradition of interaction or interdependency), have limited interaction with contiguous areas, and which, in general, have a minimum population of 20,000.

(b) The following distances will be used as guidelines in determining distances corresponding to 30 minutes travel time:

(i) Under normal conditions with primary roads available: 20 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 15 miles.

(iii) In flat terrain or in areas connected by interstate highways: 25 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 30 minutes travel time.

2. *Population Count.*

The population count used will be the total permanent resident civilian population of the area, excluding inmates of institutions, with the following adjustments, where appropriate:

(a) Adjustments to the population for the differing health service requirements of various age-sex population groups will be computed using the table below of visit rates for 12 age-sex population cohorts. The total expected visit rate will first be obtained by multiplying each of the 12 visit rates in the table by the size of the area population within that particular age-sex cohort and adding the resultant 12 visit figures together. This total expected visit rate will then be divided by the U.S. average per capita visit rate of 5.1, to obtain the adjusted population for the area.

Sex	Age groups					
	Under 5	5–14	15–24	25–44	45–64	65 and over
Male	7.3	3.6	3.3	3.6	4.7	6.4
Female	6.4	3.2	5.5	6.4	6.5	6.8

(b) The effect of transient populations on the need of an area for primary care professional(s) will be taken into account as follows:

(i) Seasonal residents, i.e., those who maintain a residence in the area but inhabit it for only 2 to 8 months per year, may be included but must be weighted in proportion to the fraction of the year they are present in the area.

(ii) Other tourists (non-resident) may be included in an area's population but only with a weight of 0.25, using the following formula: Effective tourist contribution to population=0.25×(fraction of year tourists are present in area)×(average daily number of tourists during portion of year that tourists are present).

(iii) Migratory workers and their families may be included in an area's population, using the following formula: Effective migrant contribution to population=(fraction of year migrants are present in area)×(average daily number of migrants during portion of year that migrants are present).

3. *Counting of Primary Care Practitioners.*

(a) All non-Federal doctors of medicine (M.D.) and doctors of osteopathy (D.O.) providing direct patient care who practice principally in one of the four primary care specialities—general or family practice, general internal medicine, pediatrics, and obstetrics and gynecology—will be counted. Those physicians engaged solely in administration, research, and teaching will be excluded. Adjustments for the following factors will be made in computing the number of full-time-equivalent (FTE) primary care physicians:

(i) Interns and residents will be counted as 0.1 full-time equivalent (FTE) physicians.

(ii) Graduates of foreign medical schools who are not citizens or lawful permanent residents of the United States will be excluded from physician counts.

(iii) Those graduates of foreign medical schools who are citizens or lawful permanent residents of the United States, but do not have unrestricted licenses to practice medicine, will be counted as 0.5 FTE physicians.

(b) Practitioners who are semi-retired, who operate a reduced practice due to infirmity or other limiting conditions, or who provide patient care services to the residents of the area only on a part-time basis will be discounted through the use of full-time equivalency figures. A 40-hour work week will be used as the standard for determining full-time equivalents in these cases. For practitioners working less than a 40-hour week, every four (4) hours (or ½ day) spent providing patient care, in either ambulatory or inpatient settings, will be counted as 0.1 FTE (with numbers obtained for FTE's rounded to the nearest 0.1 FTE), and each physician providing patient care 40 or more hours a week will be counted as 1.0 FTE physician. (For cases where data are available only for the

number of hours providing patient care in office settings, equivalencies will be provided in guidelines.)

(c) In some cases, physicians located within an area may not be accessible to the population of the area under consideration. Allowances for physicians with restricted practices can be made, on a case-by-case basis. However, where only a portion of the population of the area cannot access existing primary care resources in the area, a population group designation may be more appropriate (see part II of this appendix).

(d) Hospital staff physicians involved exclusively in inpatient care will be excluded. The number of full-time equivalent physicians practicing in organized outpatient departments and primary care clinics will be included, but those in emergency rooms will be excluded.

(e) Physicians who are suspended under provisions of the Medicare-Medicaid Anti-Fraud and Abuse Act for a period of eighteen months or more will be excluded.

4. *Determination of Unusually High Needs for Primary Medical Care Services.*

An area will be considered as having unusually high needs for primary health care services if at least one of the following criteria is met:

(a) The area has more than 100 births per year per 1,000 women aged 15–44.

(b) The area has more than 20 infant deaths per 1,000 live births.

(c) More than 20% of the population (or of all households) have incomes below the poverty level.

5. *Determination of Insufficient Capacity of Existing Primary Care Providers.*

An area's existing primary care providers will be considered to have insufficient capacity if at least two of the following criteria are met:

(a) More than 8,000 office or outpatient visits per year per FTE primary care physician serving the area.

(b) Unusually long waits for appointments for routine medical services (i.e., more than 7 days for established patients and 14 days for new patients).

(c) Excessive average waiting time at primary care providers (longer than one hour where patients have appointments or two hours where patients are treated on a first-come, first-served basis).

(d) Evidence of excessive use of emergency room facilities for routine primary care.

(e) A substantial proportion (2/3 or more) of the area's physicians do not accept new patients.

(f) Abnormally low utilization of health services, as indicated by an average of 2.0 or less office visits per year on the part of the area's population.

6. *Contiguous Area Considerations.*

Primary care professional(s) in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Primary care professional(s) in the contiguous area are more than 30 minutes travel time from the population center(s) of the area being considered for designation (measured in accordance with paragraph B.1(b) of this part).

(b) The contiguous area population-to-full-time-equivalent primary care physician ratio is in excess of 2000:1, indicating that practitioners in the contiguous area cannot be expected to help alleviate the shortage situation in the area being considered for designation.

(c) Primary care professional(s) in the contiguous area are inaccessible to the population of the area under consideration because of specified access barriers, such as:

(i) Significant differences between the demographic (or socio-economic) characteristics of the area under consideration and those of the contiguous area, indicating that the population of the area under consideration may be effectively isolated from nearby resources. This isolation could be indicated, for example, by an unusually high proportion of non-English-speaking persons.

(ii) A lack of economic access to contiguous area resources, as indicated particularly where a very high proportion of the population of the area under consideration is poor (i.e., where more than 20 percent of the population or the households have incomes below the poverty level), and Medicaid-covered or public primary care services are not available in the contiguous area.

C. *Determination of Degree of Shortage.*

Designated areas will be assigned to degree-of-shortage groups, based on the ratio (R) of population to number of full-time equivalent primary care physicians and the presence or absence of unusually high needs for primary health care services, according to the following table:

	High needs not indicated	High needs indicated
Group 1	No physicians	No physicians; or R≥5,000
Group 2	R≥5,000	5,000>R≥4,000
Group 3	5,000>R≥4,000	4,000>R≥3,500
Group 4	4,000>R≥3,500	3,500>R≥3,000

D. *Determination of size of primary care physician shortage.* Size of Shortage (in number of FTE primary care physicians needed) will be computed using the following formulas:

(1) For areas without unusually high need or insufficient capacity:

Primary care physician shortage=area population/3,500−number of FTE primary care physicians

(2) For areas with unusually high need or insufficient capacity:

Primary care physician shortage=area population/3,000−number of FTE primary care physicians

Part II—Population Groups

A. *Criteria.*

1. In general, specific population groups within particular geographic areas will be designated as having a shortage of primary medical care professional(s) if the following three criteria are met:

(a) The area in which they reside is rational for the delivery of primary medical care services, as defined in paragraph B.1 of part I of this appendix.

(b) Access barriers prevent the population group from use of the area's primary medical care providers. Such barriers may be economic, linguistic, cultural, or architectural, or could involve refusal of some providers to accept certain types of patients or to accept Medicaid reimbursement.

(c) The ratio of the number of persons in the population group to the number of primary care physicians practicing in the area and serving the population group is at least 3,000 : 1.

2. Indians and Alaska Natives will be considered for designation as having shortages of primary care professional(s) as follows:

(a) Groups of members of Indian tribes (as defined in section 4(d) of Pub. L. 94–437, the Indian Health Care Improvement Act of 1976) are automatically designated.

(b) Other groups of Indians or Alaska Natives (as defined in section 4(c) of Pub. L. 94–437) will be designated if the general criteria in paragraph A are met.

B. *Determination of Degree of Shortage.*

Each designated population group will be assigned to a degree-of-shortage group, based on the ratio (R) of the group's population to the number of primary care physicians serving it, as follows:

Group 1—No physicians or R>5,000.
Group 2—5,000>R≥4,000.
Group 3—4,000>R≥3,500.
Group 4—3,500>R≥3,000.

Population groups which have received ''automatic'' designation will be assigned to degree-of-shortage group 4 if no information on the ratio of the number of persons in the group to the number of FTE primary care physicians serving them is provided.

C. *Determination of size of primary care physician shortage.* Size of shortage (in number of primary care physicians needed) will be computed as follows:

Primary care physician shortage=number of persons in population group/3,000−number of FTE primary care physicians

Part III—Facilities

A. *Federal and State Correctional Institutions.*

1. *Criteria.*

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as having a shortage of primary medical care professional(s) if both the following criteria are met:

(a) The institution has at least 250 inmates.

(b) The ratio of the number of internees per year to the number of FTE primary care physicians serving the institution is at least 1,000:1. (Here the number of internees is the number of inmates present at the beginning of the year plus the number of new inmates entering the institution during the year, including those who left before the end of the year; the number of FTE primary care physicians is computed as in part I, section B, paragraph 3 above.)

2. *Determination of Degree of Shortage.*

Designated correctional institutions will be assigned to degree-of-shortage groups based on the number of inmates and/or the ratio (R) of internees to primary care physicians, as follows:

Group 1—Institutions with 500 or more inmates and no physicians.
Group 2—Other institutions with no physicians and institutions with R≥2,000.
Group 3—Institutions with 2,000>R≥1,000.

B. *Public or Non-Profit Medical Facilities.*

1. *Criteria.*

Public or non-profit private medical facilities will be designated as having a shortage of primary medical care professional(s) if:

(a) the facility is providing primary medical care services to an area or population group designated as having a primary care professional(s) shortage; and

(b) the facility has insufficient capacity to meet the primary care needs of that area or population group.

2. *Methodology*

In determining whether public or nonprofit private medical facilities meet the criteria established by paragraph B.1 of this Part, the following methodology will be used:

(a) *Provision of Services to a Designated Area or Population Group.*

A facility will be considered to be providing services to a designated area or population group if either:

(i) A majority of the facility's primary care services are being provided to residents of designated primary care professional(s) shortage areas or to population groups designated as having a shortage of primary care professional(s); or

(ii) The population within a designated primary care shortage area or population group

has reasonable access to primary care services provided at the facility. Reasonable access will be assumed if the area within which the population resides lies within 30 minutes travel time of the facility and non-physical barriers (relating to demographic and socioeconomic characteristics of the population) do not prevent the population from receiving care at the facility.

Migrant health centers (as defined in section 319(a)(1) of the Act) which are located in areas with designated migrant population groups and Indian Health Service facilities are assumed to be meeting this requirement.

(b) *Insufficient capacity to meet primary care needs.*

A facility will be considered to have insufficient capacity to meet the primary care needs of the area or population it serves if at least two of the following conditions exist at the facility:

(i) There are more than 8,000 outpatient visits per year per FTE primary care physician on the staff of the facility. (Here the number of FTE primary care physicians is computed as in Part I, Section B, paragraph 3 above.)

(ii) There is excessive usage of emergency room facilities for routine primary care.

(iii) Waiting time for appointments is more than 7 days for established patients or more than 14 days for new patients, for routine health services.

(iv) Waiting time at the facility is longer than 1 hour where patients have appointments or 2 hours where patients are treated on a first-come, first-served basis.

3. *Determination of Degree of Shortage.*

Each designated medical facility will be assigned to the same degree-of-shortage group as the designated area or population group which it serves.

[45 FR 76000, Nov. 17, 1980, as amended at 54 FR 8737, Mar. 2, 1989; 57 FR 2480, Jan. 22, 1992]

APPENDIX B TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF DENTAL PROFESSIONAL(S)

Part I—Geographic Areas

A. *Federal and State Correctional Institutions.*

1. *Criteria*

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as having a shortage of dental professional(s) if both the following criteria are met:

(a) The institution has at least 250 inmates.

(b) The ratio of the number of internees per year to the number of FTE dentists serving the institution is at least 1,500:1.

Here the number of internees is defined as follows:

(i) If the number of new inmates per year and the average length-of-stay are not specified, or if the information provided does not indicate that intake dental examinations are routinely performed by dentists upon entry, then—Number of internees=average number of inmates.

(ii) If the average length-of-stay is specified as one year or more, and intake dental examinations are routinely performed upon entry, then—Number of internees=average number of inmates+number of new inmates per year.

(iii) If the average length-of-stay is specified as less than one year, and intake dental examinations are routinely performed upon entry, then—Number of internees=average number of inmates+⅓×(1+2×ALOS)×number of new inmates per year where ALOS=average length-of-stay (in fraction of year).

(The number of FTE dentists is computed as in part I, section B, paragraph 3 above.)

2. Determination of Degree of Shortage.

Designated correctional institutions will be assigned to degree-of-shortage groups based on the number of inmates and/or the ratio (R) of internees to dentists, as follows:

Group 1—Institutions with 500 or more inmates and no dentists.

Group 2—Other institutions with no dentists and institutions with R greater than (or equal to) 3,000:1.

Group 3—Institutions with R greater than (or equal to) 1,500:1 but less than 3,000:1.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

1. *Rational Area for the Delivery of Dental Services.*

(a) The following areas will be considered rational areas for the delivery of dental health services:

(i) A county, or a group of several contiguous counties whose population centers are within 40 minutes travel time of each other.

(ii) A portion of a county (or an area made up of portions of more than one county) whose population, because of topography, market or transportation patterns, distinctive population characteristics, or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes to such resources.

(iii) Established neighborhoods and communities within metropolitan areas which display a strong self-identity (as indicated by a homogenous socioeconomic or demographic structure and/or a traditional of interaction or intradependency), have limited interaction with contiguous areas, and which, in general, have a minimum population of 20,000.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 40 minutes travel time.

2. *Population Count.*

The population count use will be the total permanent resident civilian population of the area, excluding inmates of institutions, with the following adjustments:

(a) Seasonal residents, i.e., those who maintain a residence in the area but inhabit it for only 2 to 8 months per year, may be included but must be weighted in proportion to the fraction of the year they are present in the area.

(b) Migratory workers and their families may be included in an area's population using the following formula: Effective migrant contribution to population=(fraction of year migrants are present in area)×(average daily number of migrants during portion of year that migrants are present).

3. *Counting of Dental Practitioners.*

(a) All non-Federal dentists providing patient care will be counted, except in those areas where it is shown that specialists (those dentists not in general practice or pedodontics) are serving a larger area and are not addressing the general dental care needs of the area under consideration.

(b) Full-time equivalent (FTE) figures will be used to reflect productivity differences among dental practices based on the age of the dentists, the number of auxiliaries employed, and the number of hours worked per week. In general, the number of FTE dentists will be computed using weights obtained from the matrix in Table 1, which is based on the productivity of dentists at various ages, with different numbers of auxiliaries, as compared with the average productivity of all dentists. For the purposes of these determinations, an auxiliary is defined as any non-dentist staff employed by the dentist to assist in operation of the practice.

TABLE 1—EQUIVALENCY WEIGHTS, BY AGE AND NUMBER OF AUXILIARIES

	<55	55–59	60–64	65+
No auxiliaries	0.8	0.7	0.6	0.5
One auxiliary	1.0	0.9	0.8	0.7
Two auxiliaries	1.2	1.0	1.0	0.8
Three auxiliaries	1.4	1.2	1.0	1.0
Four or more auxiliaries	1.5	1.5	1.3	1.2

If information on the number of auxiliaries employed by the dentist is not available, Table 2 will be used to compute the number of full-time equivalent dentists.

TABLE 2—EQUIVALENCY WEIGHTS, BY AGE

	55	55–59	60–64	65+
Equivalency weights	1.2	0.9	0.8	0.6

The number of FTE dentists within a particular age group (or age/auxiliary group) will be obtained by multiplying the number of dentists within that group by its corresponding equivalency weight. The total supply of FTE dentists within an area is then computed as the sum of those dentists within each age (or age/auxiliary) group.

(c) The equivalency weights specified in tables 1 and 2 assume that dentists within a particular group are working full-time (40 hours per week). Where appropriate data are available, adjusted equivalency figures for dentists who are semi-retired, who operate a reduced practice due to infirmity or other limiting conditions, or who are available to the population of an area only on a part-time basis will be used to reflect the reduced availability of these dentists. In computing these equivalency figures, every 4 hours (or ½ day) spent in the dental practice will be counted as 0.1 FTE except that each dentist working more than 40 hours a week will be counted as 1.0. The count obtained for a particular age group of dentists will then be multiplied by the appropriate equivalency weight from table 1 or 2 to obtain a full-time equivalent figure for dentists within that particular age or age/auxiliary category.

4. *Determination of Unusually High Needs for Dental Services.*

An area will be considered as having unusually high needs for dental services if at least one of the following criteria is met:

(a) More than 20% of the population (or of all households) has incomes below the poverty level.

(b) The majority of the area's population does not have a fluoridated water supply.

5. *Determination of Insufficient Capacity of Existing Dental Care Providers.*

An area's existing dental care providers will be considered to have insufficient capacity if at least two of the following criteria are met:

(a) More than 5,000 visits per year per FTE dentist serving the area.

(b) Unusually long waits for appointments for routine dental services (i.e., more than 6 weeks).

(c) A substantial proportion (⅔ or more) of the area's dentists do not accept new patients.

6. *Contiguous Area Considerations.*

Dental professional(s) in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Dental professional(s) in the contiguous area are more than 40 minutes travel time from the center of the area being considered for designation (measured in accordance with Paragraph B.1.(b) of this part).

(b) Contiguous area population-to-(FTE) dentist ratios are in excess of 3,000:1, indicating that resources in contiguous areas cannot be expected to help alleviate the shortage situation in the area being considered for designation.

(c) Dental professional(s) in the contiguous area are inaccessible to the population of the area under consideration because of specified access barriers, such as:

(i) Significant differences between the demographic (or socioeconomic) characteristics of the area under consideration and those of the contiguous area, indicating that the population of the area under consideration may be effectively isolated from nearby resources. Such isolation could be indicated, for example, by an unusually high proportion of non-English-speaking persons.

(ii) A lack of economic access to contiguous area resources, particularly where a very high proportion of the population of the area under consideration is poor (i.e., where more than 20 percent of the population or of the households have incomes below the poverty level) and Medicaid-covered or public dental services are not available in the contiguous area.

C. *Determination of Degree of Shortage.*

The degree of shortage of a given geographic area, designated as having a shortage of dental professional(s), will be determined using the following procedure:

Designated areas will be assigned to degree-of-shortage groups, based on the ratio (R) of population to number of full-time-equivalent dentists and the presence or absence of unusually high needs for dental services, or insufficient capacity of existing dental care providers according to the following table:

	High needs or insufficient capacity not indicated	High needs or insufficient capacity indicated
Group 1	No dentists	No dentists or R≥8,000.
Group 2	R≥8,000	8,000>R≥6,000.
Group 3	8,000>R≥6,000	6,000>R≥5,000.
Group 4	6,000>R≥5,000	5,000>R≥4,000.

D. *Determination of size of dental shortage.* Size of Dental Shortage (in number of FTE dental practitioners needed) will be computed using the following formulas:

(1) For areas without unusually high need:

Dental shortage=area population/5,000−number of FTE dental practitioners

(2) For areas with unusually high need:

Dental shortage=area population/4,000−number of FTE dental practitioners

Part II—Population Groups

A. *Criteria.*

1. In general, specified population groups within particular geographic areas will be designated as having a shortage of dental care professional(s) if the following three criteria are met:

a. The area in which they reside is rational for the delivery of dental care services, as defined in paragraph B.1 of part I of this appendix.

b. Access barriers prevent the population group from use of the area's dental providers.

c. The ratio (R) of the number of persons in the population group to the number of dentists practicing in the area and serving the population group is at least 4,000:1.

2. Indians and Alaska Natives will be considered for designation as having shortages of dental professional(s) as follows:

(a) Groups of members of Indian tribes (as defined in section 4(d) of Pub. L. 94–437, the Indian Health Care Improvement Act of 1976) are automatically designated.

(b) Other groups of Indians or Alaska Natives (as defined in section 4(c) of Pub. L. 94–437) will be designated if the general criteria in paragraph 1 are met.

B. *Determination of Degree of Shortage.*

Each designated population group will be assigned to a degree-of-shortage group as follows:

Group 1—No dentists or R≥8,000.
Group 2—8,000>R≥6,000.
Group 3—6,000>R≥5,000.
Group 4—5,000>R≥4,000.

Population groups which have received ''automatic'' designation will be assigned to degree-of-shortage group 4 unless information on the ratio of the number of persons in the group to the number of FTE dentists serving them is provided.

C. *Determination of size of dental shortage.* Size of dental shortage will be computed as follows:

Dental shortage=number of persons in population group/4,000−number of FTE dental practitioners

Part III—Facilities

A. *Federal and State Correctional Institutions.*

1. *Criteria.*

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as having a shortage of dental professional(s) if both the following criteria are met:

(a) The institution has at least 250 inmates.

(b) The ratio of the number of internees per year to the number of FTE dentists serving the institution is at least 1,500:1. (Here the number of internees is the number of inmates present at the beginning of the year plus the number of new inmates entering the institution during the year, including those who left before the end of the year; the number of FTE dentists is computed as in part I, section B, paragraph 3 above.)

2. *Determination of Degree-of-Shortage.*

Designated correctional institutions will be assigned to degree-of-shortage groups as follows, based on number of inmates and/or the ratio (R) of internees to dentists:

Group 1—Institutions with 500 or more inmates and no dentists.
Group 2—Other institutions with no dentists and institutions with R > 3,000.
Group 3—Institutions with 3,000 > R > 1,500.

B. *Public or Non-Profit Private Dental Facilities.*

1. *Criteria.*

Public or nonprofit private facilties providing general dental care services will be designated as having a shortage of dental professional(s) if both of the following criteria are met:

(a) The facility is providing general dental care services to an area or population group designated as having a dental professional(s) shortage; and

(b) The facility has insufficent capacity to meet the dental care needs of that area or population group.

2. *Methodology.*

In determining whether public or nonprofit private facilities meet the criteria established by paragraph B.1. of this part, the following methodology will be used:

(a) *Provision of Services to a Designated Area or Population Group.*

A facility will be considered to be providing services to an area or population group if either:

(i) A majority of the facility's dental care services are being provided to residents of designated dental professional(s) shortage areas or to population groups designated as having a shortage of dental professional(s); or

(ii) The population within a designated dental shortage area or population group has reasonable access to dental services provided at the facility. Reasonable access will be assumed if the population lies within 40 minutes travel time of the facility and non-physical barriers (relating to demographic and socioeconomic characteristics of the population) do not prevent the population from receiving care at the facility.

Migrant health centers (as defined in section 319(a)(1) of the Act) which are located in areas with designated migrant population groups and Indian Health Service facilities are assumed to be meeting this requirement.

(b) *Insufficient Capacity To Meet Dental Care Needs.*

A facility will be considered to have insufficient capacity to meet the dental care needs of a designated area or population group if either of the following conditions exists at the facility.

(i) There are more than 5,000 outpatient visits per year per FTE dentist on the staff of the facility. (Here the number of FTE dentists is computed as in part I, section B, paragraph 3 above.)

(ii) Waiting time for appointments is more than 6 weeks for routine dental services.

3. *Determination of Degree of Shortage.*

Each designated dental facility will be assigned to the same degree-of-shortage group as the designated area or population group which it serves.

[45 FR 76000, Nov. 17, 1980, as amended at 54 FR 8738, Mar. 2, 1989; 57 FR 2480, Jan. 22, 1992]

APPENDIX C TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF MENTAL HEALTH PROFESSIONALS

Part I—Geographic Areas

A. *Criteria.* A geographic area will be designated as having a shortage of mental health professionals if the following four criteria are met:

1. The area is a rational area for the delivery of mental health services.

2. One of the following conditions prevails within the area:

(a) The area has—

(i) A population-to-core-mental-health-professional ratio greater than or equal to 6,000:1 and a population-to-psychiatrist ratio greater than or equal to 20,000:1, or

(ii) A population-to-core-professional ratio greater than or equal to 9,000:1, or

(iii) A population-to-psychiatrist ratio greater than or equal to 30,000:1;

(b) The area has unusually high needs for mental health services, and has—

(i) A population-to-core-mental-health-professional ratio greater than or equal to 4,500:1 and

A population-to-psychiatrist ratio greater than or equal to 15,000:1, or

(ii) A population-to-core-professional ratio greater than or equal to 6,000:1, or

(iii) A population-to-psychiatrist ratio greater than or equal to 20,000:1;

3. Mental health professionals in contiguous areas are overutilized, excessively distant or inaccessible to residents of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

1. *Rational Areas for the Delivery of Mental Health Services.*

(a) The following areas will be considered rational areas for the delivery of mental health services:

(i) An established mental health catchment area, as designated in the State Mental Health Plan under the general criteria set forth in section 238 of the Community Mental Health Centers Act.

(ii) A portion of an established mental health catchment area whose population, because of topography, market and/or transportation patterns or other factors, has limited access to mental health resources in the rest of the catchment area, as measured generally by a travel time of greater than 40 minutes to these resources.

(iii) A county or metropolitan area which contains more than one mental health catchment area, where data are unavailable by individual catchment area.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 40 minutes travel time.

2. *Population Count.*

The population count used will be the total permanent resident civilian population of the area, excluding inmates of institutions.

3. *Counting of mental health professionals.* (a) All non-Federal core mental health professionals (as defined below) providing mental health patient care (direct or other, including consultation and supervision) in ambulatory or other short-term care settings to residents of the area will be counted. Data on each type of core professional should be presented separately, in terms of the number of full-time-equivalent (FTE) practitioners of each type represented.

(b) Definitions:

(i) *Core mental health professionals* or *core professionals* includes those psychiatrists, clinical psychologists, clinical social workers, psychiatric nurse specialists, and marriage and family therapists who meet the definitions below.

(ii) *Psychiatrist* means a doctor of medicine (M.D.) or doctor of osteopathy (D.O.) who

(A) Is certified as a psychiatrist or child psychiatrist by the American Medical Specialities Board of Psychiatry and Neurology or by the American Osteopathic Board of Neurology and Psychiatry, or, if not certified, is ''broad-eligible'' (i.e., has successfully completed an accredited program of graduate medical or osteopathic education in psychiatry or child psychiatry); and

(B) Practices patient care psychiatry or child psychiatry, and is licensed to do so, if required by the State of practice.

(iii) *Clinical psychologist* means an individual (normally with a doctorate in psychology) who is practicing as a clinical or counseling psychologist and is licensed or certified to do so by the State of practice; or, if licensure or certification is not required in the State of practice, an individual with a doctorate in psychology and two years of supervised clinical or counseling experience. (School psychologists are not included.)

(iv) *Clinical social worker* means an individual who—

(A) Is certified as a clinical social worker by the American Board of Examiners in Clinical Social Work, or is listed on the National Association of Social Workers' Clinical Register, or has a master's degree in social work and two years of supervised clinical experience; and

(B) Is licensed to practice as a social worker, if required by the State of practice.

(v) *Psychiatric nurse specialist* means a registered nurse (R.N.) who—

(A) Is certified by the American Nurses Association as a psychiatric and mental health clinical nurse specialist, or has a master's degree in nursing with a specialization in psychiatric/mental health and two years of supervised clinical experience; and

(B) Is licensed to practice as a psychiatric or mental health nurse specialist, if required by the State of practice.

(vi) *Marriage and family therapist* means an individual (normally with a master's or doctoral degree in marital and family therapy and at least two years of supervised clinical experience) who is practicing as a marital and family therapist and is licensed or certified to do so by the State of practice; or, if licensure or certification is not required by the State of practice, is eligible for clinical membership in the American Association for Marriage and Family Therapy.

(c) Practitioners who provide patient care to the population of an area only on a part-time basis (whether because they maintain another office elsewhere, spend some of their time providing services in a facility, are semi-retired, or operate a reduced practice for other reasons), will be counted on a partial basis through the use of full-time-equivalency calculations based on a 40-hour

week. Every 4 hours (or ½ day) spent providing patient care services in ambulatory or inpatient settings will be counted as 0.1 FTE, and each practitioner providing patient care for 40 or more hours per week as 1.0 FTE. Hours spent on research, teaching, vocational or educational counseling, and social services unrelated to mental health will be excluded; if a practitioner is located wholly or partially outside the service area, only those services actually provided within the area are to be counted.

(d) In some cases, practitioners located within an area may not be accessible to the general population of the area under consideration. Practitioners working in restricted facilities will be included on an FTE basis based on time spent outside the facility. Examples of restricted facilities include correctional institutions, youth detention facilities, residential treatment centers for emotionally disturbed or mentally retarded children, school systems, and inpatient units of State or county mental hospitals.

(e) In cases where there are mental health facilities or institutions providing both inpatient and outpatient services, only those FTEs providing mental health services in outpatient units or other short-term care units will be counted.

(f) Adjustments for the following factors will also be made in computing the number of FTE providers:

(i) Practitioners in residency programs will be counted as 0.5 FTE.

(ii) Graduates of foreign schools who are not citizens or lawful permanent residents of the United States will be excluded from counts.

(iii) Those graduates of foreign schools who are citizens or lawful permanent residents of the United States, and practice in certain settings, but do not have unrestricted licenses to practice, will be counted on a full-time-equivalency basis up to a maximum of 0.5 FTE.

(g) Practitioners suspended for a period of 18 months or more under provisions of the Medicare-Medicaid Anti-Fraud and Abuse Act will not be counted.

4. *Determination of unusually high needs for mental health services.* An area will be considered to have unusually high needs for mental health services if one of the following criteria is met:

(a) 20 percent of the population (or of all households) in the area have incomes below the poverty level.

(b) The youth ratio, defined as the ratio of the number of children under 18 to the number of adults of ages 18 to 64, exceeds 0.6.

(c) The elderly ratio, defined as the ratio of the number of persons aged 65 and over to the number of adults of ages 18 to 64, exceeds 0.25.

(d) A high prevalence of alcoholism in the population, as indicated by prevalence data showing the area's alcoholism rates to be in the worst quartile of the nation, region, or State.

(e) A high degree of substance abuse in the area, as indicated by prevalence data showing the area's substance abuse to be in the worst quartile of the nation, region, or State.

5. *Contiguous area considerations.* Mental health professionals in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Core mental health professionals in the contiguous area are more than 40 minutes travel time from the closest population center of the area being considered for designation (measured in accordance with paragraph B.1(b) of this part).

(b) The population-to-core-mental-health-professional ratio in the contiguous area is in excess of 3,000:1 and the population-to-psychiatrist ratio there is in excess of 10,000:1, indicating that core mental health professionals in the contiguous areas are overutilized and cannot be expected to help alleviate the shortage situation in the area for which designation is being considered. (If data on core mental health professionals other than psychiatrists are not available for the contiguous area, a population-to-psychiatrist ratio there in excess of 20,000:1 may be used to demonstrate overutilization.)

(c) Mental health professionals in contiguous areas are inaccessible to the population of the requested area due to geographic, cultural, language or other barriers or because of residency restrictions of programs or facilities providing such professionals.

C. *Determination of degree of shortage.* Designated areas will be assigned to degree-of-shortage groups according to the following table, depending on the ratio (R_C) of population to number of FTE core-mental-health-service providers (FTE_C); the ratio (R_P) of population to number of FTE psychiatrists (FTE_P); and the presence or absence of high needs:

High Needs Not Indicated

Group 1—FTE_C=0 and FTE_P=0

Group 2—R_C gte * 6,000:1 and FTE_P=0

Group 3—R_C gte 6,000:1 and R_P gte 20,000

Group 4(a)—For psychiatrist placements only: All other areas with FTE_P=0 or R_P gte 30,000

Group 4(b)—For other mental health practitioner placements: All other areas with R_C gte 9,000:1.

*Note: ''gte'' means ''greater than or equal to''.

High Needs Indicated

Group 1—FTE_C=0 and FTE_P=0
Group 2—R_C gte 4,500:1 and FTE_P=0
Group 3—R_C gte 4,500:1 and R_P gte 15,000
Group 4(a)—For psychiatrist placements only: All other areas with FTE_P=0 or R_P gte 20,000
Group 4(b)—For other mental health practitioner placements: All other areas with R_C gte 6,000:1.

D. *Determination of Size of Shortage.* Size of Shortage (in number of FTE professionals needed) will be computed using the following formulas:

(1) For areas without unusually high need:

Core professional shortage=area population/6,000−number of FTE core professionals
Psychiatrist shortage=area population/20,000−number of FTE psychiatrists

(2) For areas with unusually high need:

Core professional shortage=area population/4,500−number of FTE core professionals
Psychiatrist shortage=area population/15,000−number of FTE psychiatrists

Part II—Population Groups

A. *Criteria.* Population groups within particular rational mental health service areas will be designated as having a mental health professional shortage if the following criteria are met:

1. Access barriers prevent the population group from using those core mental health professionals which are present in the area; and

2. One of the following conditions prevails:

(a) The ratio of the number of persons in the population group to the number of FTE core mental health professionals serving the population group is greater than or equal to 4,500:1 and the ratio of the number of persons in the population group to the number of FTE psychiatrists serving the population group is greater than or equal to 15,000:1; or,

(b) The ratio of the number of persons in the population group to the number of FTE core mental health professionals serving the population group is greater than or equal to 6,000:1; or,

(c) The ratio of the number of persons in the population group to the number of FTE psychiatrists serving the population group is greater than or equal to 20,000:1.

B. *Determination of degree of shortage.* Designated population groups will be assigned to the same degree-of-shortage groups defined in part I.C of this appendix for areas with unusually high needs for mental health services, using the computed ratio (R_C) of the number of persons in the population group to the number of FTE core mental health service providers (FTE_C) serving the population group, and the ration (R_P) of the number of persons in the population group to the number of FTE psychiatrists (FTE_P) serving the population group.

C. *Determination of size of shortage.* Size of shortage will be computed as follows:

Core professional shortage=number of persons in population group/4,500−number of FTE core professionals
Psychiatrist shortage=number of persons in population group/15,000−number of FTE psychiatrists

Part III—Facilities

A. *Federal and State Correctional Institutions*

1. *Criteria.*

Medium to maximum security Federal and State correctional institutions for adults or youth, and youth detention facilities, will be designated as having a shortage of psychiatric professional(s) if both of the following criteria are met:

(a) The institution has more than 250 inmates, and

(b) The ratio of the number of internees per year to the number of FTE psychiatrists serving the institution is at least 2,000:1. (Here the number of internees is the number of inmates or residents present at the beginning of the year, plus the number of new inmates or residents entering the institution during the year, including those who left before the end of the year; the number of FTE psychiatrists is computed as in part I, section B, paragraph 3 above.)

2. *Determination of Degree of Shortage.*

Correctional facilities and youth detention facilities will be assigned to degree-of-shortage groups, based on the number of inmates and/or the ratio (R) of internees to FTE psychiatrists, as follows:

Group 1—Facilities with 500 or more inmates or residents and no psychiatrist.

Group 2—Other facilities with no psychiatrists and facilities with 500 or more inmates or residents and R>3,000.

Group 3—All other facilities.

B. *State and County Mental Hospitals.*

1. *Criteria.*

A State or county hospital will be designated as having a shortage of psychiatric professional(s) if both of the following criteria are met:

(a) The mental hospital has an average daily inpatient census of at least 100; and

(b) The number of workload units per FTE psychiatrists available at the hospital exceeds 300, where workload units are calculated using the following formula:

Total workload units = average daily inpatient census + 2 × (number of inpatient admissions per year) + 0.5 × (number of admissions to day care and outpatient services per year).

2. *Determination of Degree of Shortage.*

State or county mental hospitals will be assigned to degree-of-shortage groups, based

on the ratio (R) of workload units to number of FTE psychiatrists, as follows:

Group 1—No psychiatrists, or R>1,800.
Group 2—1,800>R>1,200.
Group 3—1,200>R>600.
Group 4—600>R>300.

C. *Community Mental Health Centers and Other Public or Nonprofit Private Facilities.*

1. *Criteria.*

A community mental health center (CMHC), authorized by Pub. L. 94–63, or other public or nonprofit private facility providing mental health services to an area or population group, may be designated as having a shortage of psychiatric professional(s) if the facility is providing (or is responsible for providing) mental health services to an area or population group designated as having a mental health professional(s), and the facility has insufficient capacity to meet the psychiatric needs of the area or population group.

2. *Methodology.*

In determining whether CMHCs or other public or nonprofit private facilities meet the criteria established in paragraph C.1 of this Part, the following methodology will be used.

(a) *Provision of Services to a Designated Area or Population Group.*

The facility will be considered to be providing services to a designated area or population group if either:

(i) A majority of the facility's mental health services are being provided to residents of designated mental health professional(s) shortage areas or to population groups designated as having a shortage of mental health professional(s); or

(ii) The population within a designated psychiatric shortage area or population group has reasonable access to mental health services provided at the facility. Such reasonable access will be assumed if the population lies within 40 minutes travel time of the facility and nonphysical barriers (relating to demographic and socioeconomic characteristics of the population) do not prevent the population from receiving care at the facility.

(b) *Responsibility for Provision of Services.*

This condition will be considered to be met if the facility, by Federal or State statute, administrative action, or contractual agreement, has been given responsibility for providing and/or coordinating mental health services for the area or population group, consistent with applicable State plans.

(c) *Insufficient capacity to meet mental health service needs.* A facility will be considered to have insufficient capacity to meet the mental health service needs of the area or population it serves if:

(i) There are more than 1,000 patient visits per year per FTE core mental health professional on staff of the facility, or

(ii) There are more than 3,000 patient visits per year per FTE psychiatrist on staff of the facility, or

(iii) No psychiatrists are on the staff and this facility is the only facility providing (or responsible for providing) mental health services to the designated area or population.

3. *Determination of Degree-of-Shortage.*

Each designated facility will be assigned to the same degree-of-shortage group as the designated area or population group which it serves.

[45 FR 76000, Nov. 17, 1980, as amended at 54 FR 8738, Mar. 2, 1989; 57 FR 2477, Jan. 22, 1992]

APPENDIX D TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF VISION CARE PROFESSIONAL(S)

Part I—Geographic Areas

A. *Criteria.*

A geographic area will be designated as having a shortage of vision care professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of vision care services.

2. The estimated number of optometric visits supplied by vision care professional(s) in the area is less than the estimated requirements of the area's population for these visits, and the computed shortage is at least 1,500 optometric visits.

3. Vision care professional(s) in contiguous areas are excessively distant, overutilized, or inaccessible to the population of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

1. *Rational Areas for the Delivery of Vision Care Services.*

(a) The following areas will be considered rational areas for the delivery of vision care services:

(i) A county, or a group of contiguous counties whose population centers are within 40 minutes travel time of each other;

(ii) A portion of a county (or an area made up of portions of more than one county) whose population, because of topography, market or transportation patterns, or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 40 minutes travel time.

2. *Determination of Estimated Requirement for Optometric Visits.*

The number of optometric visits required by an area's population will be estimated by multiplying each of the following visit rates by the size of the population within that particular age group and then adding the figures obtained together.

Age	Annual number of optometric visits required per person, by age					
	Under 20	20–29	30–39	40–49	50–59	60 and over
Number of visits	0.11	0.20	0.24	0.35	0.41	0.48

For geographic areas where the age distribution of the population is not known, it will be assumed that the percentage distribution, by age groups, for the area is the same as the distribution for the county of which it is a part.

(3) *Determination of Estimated Supply of Optometric Visits.*

The estimated supply of optometric services will be determined by use of the following formula:

Optometric visits supplied = 3,000 × (number of optometrists under 65)
Optometric visits supplied + 2,000 × (number of optometrists 65 and over)
Optometric visits supplied + 1,500 × (number of ophthamologists)

(4) *Determination of Size of Shortage.*

Size of shortage (in number of optometric visits) will be computed as follows:

Optometric visit shortage = visits required − visits supplied

(5) *Contiguous Area Considerations.*

Vision care professional(s) in area contiguous to an area being considered for designation will be considered execessively distant, overutilized or inaccessible to the population of the area if one of the following conditions prevails in each contiguous area:

(a) Vision care professional(s) in the contiguous area are more than 40 minutes travel time from the center of the area being considered for designation (measured in accordance with paragraph B.1(b) of this part).

(b) The estimated requirement for vision care services in the contiguous area exceeds the estimated supply of such services there, based on the requirements and supply calculations previously described.

(c) Vision care professional(s) in the contiguous area are inaccessible to the population of the area because of specified access barriers (such as economic or cultural barriers).

C. *Determination of Degree-of-Shortage.*

Designated areas (and population groups) will be assigned to degree-of-shortage groups, based on the ratio of optometric visits supplied to optometric visits required for the area (or group), as follows:

Group 1—Areas (or groups) with no optometric visits being supplied (i.e., with no optometrists or ophthalmologists).

Group 2—Areas (or groups) where the ratio of optometric visits supplied to optometric visits required is less than 0.5.

Group 3—Areas (or groups) where the ratio of optometric visits supplied to optometric visits required is between 0.5 and 1.0.

Part II—Population Groups

A. *Criteria.*

Population groups within particular geographic areas will be designated if both the following criteria are met:

(1) Members of the population group do not have access to vision care resources within the area (or in contiguous areas) because of non-physical access barriers (such as economic or cultural barriers).

(2) The estimated number of optometric visits supplied to the population group (as determined under paragraph B.3 of part I of this Appendix) is less than the estimated number of visits required by that group (as determined under paragraph B.2 of part I of this Appendix), and the computed shortage is at least 1,500 optometric visits.

B. *Determination of Degree of Shortage.*

The degree of shortage of a given population group will be determined in the same way as described for areas in paragraph C of part I of this appendix.

APPENDIX E TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PODIATRIC PROFESSIONAL(S)

Part I—Geographic Areas

A. *Criteria.*

A geographic area will be designated as having a shortage of podiatric professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of podiatric services.

2. The area's ratio of population to foot care practitioners is at least 28,000:1, and the computed podiatrist shortage to meet this ratio is at least 0.5.

3. Podiatric professional(s) in contiguous areas are overutilized, excessively distant, or inaccessible to the population of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this Part, the following methodology will be used:

1. *Rational Areas for the Delivery of Podiatric Services.*

(a) The following areas will be considered rational areas for the delivery of podiatric services:

(i) A county or a group of contiguous counties whose population centers are within 40 minutes travel time of each other.

(ii) A portion of a county, or an area made up of portions of more than one county, whose population, because of topography, market and/or transportation patterns or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes from its population center to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the area corresponding to 40 minutes travel time.

2. *Population Count.*

The population count used will be the total permanent resident civilian population of the area, excluding inmates of institutions, adjusted by the following formula to take into account the differing utilization rates of podiatric services by different age groups within the population:

Adjusted population=total population × (1 + 2.2 × (percent of population 65 and over) − 0.44 × (percent of population under 17)).

3. *Counting of Foot Care Practitioners.*

(a) All podiatrists providing patient care will be counted. However, in order to take into account productivity differences in podiatric practices associated with the age of the podiatrists, the following formula will be utilized:

Number of FTE podiatrists = 1.0 × (podiatrists under age 55)
+ .8 × (podiatrists age 55 and over)

(b) In order to take into account the fact that orthopedic surgeons and general and family practitioners devote a percentage of their time to foot care, the total available foot care practitioners will be computed as follows:

Number of foot care practitioners = number of FTE podiatrists
+ .15 × (number of orthopedic surgeons)
+ .02 × (number of general and family practioners).

4. *Determination of Size of Shortage.*

Size of shortage (in number of FTE podiatrists) will be computed as follows:

Podiatrist shortage = adjusted population/28,000 − number of FTE foot care practitioners.

5. *Contiguous Area Considerations.*

Podiatric professional(s) in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Podiatric professional(s) in the contiguous area are more than 40 minutes travel time from the center of the area being considered for designation.

(b) The population-to-foot care practitioner ratio in the contiguous areas is in excess of 20,000:1, indicating that contiguous area podiatric professional(s) cannot be expected to help alleviate the shortage situation in the area for which designation is requested.

(c) Podiatric professional(s) in the contiguous area are inaccessible to the population of the area under consideration because of specified access barriers (such as economic or cultural barriers).

C. *Determination of Degree of Shortage.*

Designated areas will be assigned to groups, based on the ratio (R) of adjusted population to number of foot care practitioners, as follows:

Group 1 Areas with no foot care practitioners, and areas with R > 50,000 and no podiatrists.
Group 2 Other areas with R > 50,000.
Group 3 Areas with 50,000 > R > 28,000.

APPENDIX F TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PHARMACY PROFESSIONAL(S)

Part I—Geographic Areas

A. *Criteria.*

A geographic area will be designated as having a shortage of pharmacy professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of pharmacy services.

2. The number of pharmacists serving the area is less than the estimated requirement for pharmacists in the area, and the computed pharmacist shortage is at least 0.5.

3. Pharmacists in contiguous areas are overutilized or excessively distant from the population of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this Part, the following methodology will be used:

1. *Rational Areas for the Delivery of Pharmacy Services.*

(a) The following areas will be considered rational areas for the delivery of pharmacy services:

(i) A county, or a group of contiguous counties whose population centers are within 30 minutes travel time of each other; and

(ii) A portion of a county, or an area made up of portions of more than one county, whose population, because of topography, market or transportation patterns or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 30 minutes to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 30 minutes travel time:

(i) Under normal conditions with primary roads available: 20 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 15 miles.

(iii) In flat terrain or in areas connected by interstate highways: 25 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the area corresponding to 30 minutes travel time.

2. *Counting of Pharmacists.*

All active pharmacists within the area will be counted, except those engaged in teaching, administration, or pharmaceutical research.

3. *Determination of Estimated Requirement for Pharmacists.*

(a) *Basic estimate.* The basic estimated requirement for pharmacists will be calculated as follows:

Basic pharmacist requirement = .15 × (resident civilian population/1,000) + .035 × (total number of physicians engaged in patient care in the area).

(b) *Adjusted estimate.* For areas with less than 20,000 persons, the following adjustment is made to the basic estimate to compensate for the lower expected productivity of small practices.

Estimated pharmacist requirement = (2 − population/20,000) × basic pharmacist requirement.

4. *Size of Shortage Computation.*

The size of the shortage will be computed as follows:

Pharmacist shortage = estimated pharmacist requirement − number of pharmacists available.

5. *Contiguous Area Considerations.*

Pharmacists in areas contiguous to an area being considered for designation will be considered excessively distant or overutilized if either:

(a) Pharmacy professional(s) in contiguous areas are more than 30 minutes travel time from the center of the area under consideration, or

(b) The number of pharmacists in each contiguous area is less than or equal to the estimated requirement for pharmacists for that contiguous area (as computed above).

C. *Determination of Degree-of-Shortage.*

Designated areas will be assigned to degree-of-shortage groups, based on the proportion of the estimated requirement for pharmacists which is currently available in the area, as follows:

Group 1—Areas with no pharmacists.

Group 2—Areas where the ratio of available pharmacists to pharmacists required is less than 0.5.

Group 3—Areas where the ratio of available pharmacists to pharmacists required is between 0.5 and 1.0.

APPENDIX G TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF VETERINARY PROFESSIONAL(S)

Part I—Geographic Areas

A. *Criteria for Food Animal Veterinary Shortage.*

A geographic area will be designated as having a shortage of food animal veterinary professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of veterinary services.

2. The ratio of veterinary livestock units to food animal veterinarians in the area is at least 10,000:1, and the computed food animal veterinarian shortage to meet this ratio is at least 0.5.

3. Food animal veterinarians in contiguous areas are overutilized or excessively distant from the population of the area under consideration.

B. *Criteria for Companion Animal Veterinary Shortage.*

A geographic area will be designated as having a shortage of companion animal veterinary professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of veterinary services.

2. The ratio of resident civilian population to number of companion animal veterinarians in the area is at least 30,000:1 and the computed companion animal veterinary shortage to meet this ratio is at least 0.5.

3. Companion animal veterinarians in contiguous areas are overutilized or excessively distant from the population of the area under consideration.

C. *Methodology.*

In determining whether an area meets the criteria established by paragraphs A and B of this part, the following methodology will be used:

1. *Rational Areas for the Delivery of Veterinary Services.*

(a) The following areas will be considered rational areas for the delivery of veterinary services:

(i) A county, or a group of contiguous counties whose population centers are within 40 minutes travel time of each other.

(ii) A portion of a county (or an area made up of portions of more than one county) which, because of topography, market and/or transportation patterns or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

2. *Determination of Number of Veterinary Livestock Units (VLU) Requiring Care.*

Since various types of food animals require varying amounts of veterinary care, each type of animal has been assigned a weight indicating the amount of veterinary care it requires relative to that required by a milk cow. Those weights are used to compute the number of ''Veterinary Livestock Units'' (VLU) for which veterinary care is required.

The VLU is computed as follows:

Veterinary Livestock Units (VLU)=(number of milk cows)
+.2×(number of other cattle and calves)
+.05×(number of hogs and pigs)
+.05×(number of sheep)
+.002×(number of poultry).

3. *Counting of Food Animal Veterinarians.*

The number of food animal veterinarians is determined by weighting the number of veterinarians within each of several practice categories according to the average fraction of practice time in that category which is devoted to food animal veterinary care, as follows:

Number of Food Animal Veterinarians=(number of veterinarians in large animal practice, exclusively)
+(number of veterinarians in bovine practice, exclusively)
+(number of veterinarians in poultry practice, exclusively)
+.75×(mixed practice veterinarians with greater than 50% of practice in large animal care)
+.5×(mixed practice veterinarians with approximately 50% of practice in large animal care)
+.25×(mixed practice veterinarians with less than 50% of practice in large animal care).

4. *Counting of Companion Animal Veterinarians* (that is, those who provide services for dogs, cats, horses, and any other animals maintained as companions to the owner rather than as food animals).

The number of full-time equivalent companion animal veterinarians is determined by weighting the number of veterinarians within each of several practice categories by the average portion of their practice which is devoted to companion animal care by the practitioners within that category, as follows:

Number of Companion Animal Veterinarians=(number of veterinarians in large animal practice, exclusively)
+(number of veterinarians in equine practice, exclusively)
+.75×(mixed practice veterinarians with greater than 50% of practice in small animal care)
+.5×(mixed practice veterinarians with approximately 50% of practice in small animal care)
+.25×(mixed practice veterinarians with less than 50% of practice in small animal care).

5. *Size of Shortage Computation.*

The size of shortage will be computed as follows:

(a) Food animal veterinarian shortage=(VLU/10,000)−(number of food animal veterinarians).

(b) Companion animal veterinarian shortage=(resident civilian pop./30,000)−(number of companion animal veterinarians).

6. *Contiguous Area Considerations.*

Veterinary professional(s) in areas contiguous to an area being considered for designation will be considered excessively distant from the population of the area or overutilized if one of the following conditions prevails in each contiguous area:

(a) Veterinary professional(s) in the contiguous area are more than 60 minutes travel time from the center of the area being considered for designation (measured in accordance with paragraph C.1.(b) of this part).

(b) In the case of food animal veterinary professional(s), the VLU-to-food animal veterinarian ratio in the contiguous area is in excess of 5,000:1.

(c) In the case of companion animal veterinary professional(s), the population-to-companion animal veterinarian ratio in the contiguous area is in excess of 15,000:1.

C. *Determination of Degree-of-Shortage.*

Designated areas will be assigned to degree-of-shortage groups as follows:

Group 1—Areas with a food animal veterinarian shortage and no veterinarians.

Group 2—Areas (not included above) with a food animal veterinarian shortage and no food animal veterinarians.

Group 3—All other food animal veterinarian shortage areas.

Group 4—All companion animal shortage areas (not included above) having no veterinarians.

Group 5—All other companion animal shortage areas.

PART 6—FEDERAL TORT CLAIMS ACT COVERAGE OF CERTAIN GRANTEES AND INDIVIDUALS

Sec.

AUTHORITY: Sections 215 and 224 of the Public Health Service Act, 42 U.S.C. 216 and 233.

SOURCE: 60 FR 22532, May 8, 1995, unless otherwise noted.

§6.1 Applicability.

This part applies to entities and individuals whose acts and omissions related to the performance of medical, surgical, dental, or related functions are covered by the Federal Tort Claims Act (28 U.S.C. 1346(b) and 2671–2680) in accordance with the provisions of section 224(g) of the Public Health Service Act (42 U.S.C. 233(g)).

§6.2 Definitions.

Act means the Public Health Service Act, as amended.

Attorney General means the Attorney General of the United States and any other officer or employee of the Department of Justice to whom the authority involved has been delegated.

Covered entity means an entity described in §6.3 which has been deemed by the Secretary, in accordance with §6.5, to be covered by this part.

Covered individual means an individual described in §6.4.

Effective date as used in §6.5 and §6.6 refers to the date of the Secretary's determination that an entity is a covered entity.

Secretary means the Secretary of Health and Human Services (HHS) and any other officer or employee of the Department of HHS to whom the authority involved has been delegated.

Subrecipient means an entity which receives a grant or a contract from a covered entity to provide a full range of health services on behalf of the covered entity.

§6.3 Eligible entities.

(a) *Grantees.* Entities eligible for coverage under this part are public and nonprofit private entities receiving Federal funds under any of the following grant programs:

(1) Section 329 of the Act (relating to grants for migrant health centers);

(2) Section 330 of the Act (relating to grants for community health centers);

(3) Section 340 of the Act (relating to grants for health services for the homeless); and

(4) Section 340A of the Act (relating to grants for health services for residents of public housing).

(b) *Subrecipients.* Entities that are subrecipients of grant funds described in paragraph (a) of this section are eligible for coverage only if they provide a full range of health care services on behalf of an eligible grantee and only for those services carried out under the grant funded project.

§6.4 Covered individuals.

(a) Officers and employees of a covered entity are eligible for coverage under this part.

(b) Contractors of a covered entity who are physicians or other licensed or certified health care practitioners are eligible for coverage under this part if they meet the requirements of section 224(g)(5) of the Act.

(c) An individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor of a covered entity will not be covered for acts or omissions occurring after receipt by the entity employing such individual of notice of a final determination by the Attorney General that he or she is no longer covered by this part, in accordance with section 224(i) of the Act.

§6.5 Deeming process for eligible entities.

Eligible entities will be covered by this part only on and after the effective date of a determination by the Secretary that they meet the requirements of section 224(h) of the Act. In making such determination, the Secretary will receive such assurances and conduct such investigations as he or she deems necessary.

§6.6 Covered acts and omissions.

(a) Only acts and omissions occurring on and after the effective date of the Secretary's determination under §6.5 and before the later date specified in section 224(g)(3) of the Act are covered by this part.

(b) Only claims for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions are covered by this part.

(c) With respect to covered individuals, only acts and omissions within the scope of their employment (or contract for services) are covered. If a covered individual is providing services which are not on behalf of the covered entity, such as on a volunteer basis or on behalf of a third-party (except as described in paragraph (d) of this section), whether for pay or otherwise, acts and omissions which are related to such services are not covered.

(d) Only acts and omissions related to the grant-supported activity of entities are covered. Acts and omissions related to services provided to individuals who are not patients of a covered entity will be covered only if the Secretary determines that:

(1) The provision of the services to such individuals benefits patients of the entity and general populations that could be served by the entity through community-wide intervention efforts within the communities served by such entity;

(2) The provision of the services to such individuals facilitates the provision of services to patients of the entity; or

(3) Such services are otherwise required to be provided to such individuals under an employment contract or similar arrangement between the entity and the covered individual.

(e) *Examples.* The following are examples of situations within the scope of paragraph (d) of this section:

(1) A community health center deemed to be a covered entity establishes a school-based or school-linked health program as part of its grant supported activity. Even though the students treated are not necessarily registered patients of the center, the center and its health care practitioners will be covered for services provided, if the Secretary makes the determination in paragraph (d)(1) of this section.

(2) A migrant health center requires its physicians to obtain staff privileges at a community hospital. As a condition of obtaining such privileges, and thus being able to admit the center's patients to the hospital, the physicians must agree to provide occasional coverage of the hospital's emergency room. The Secretary would be authorized to determine that this coverage is necessary to facilitate the provision of services to the grantee's patients, and that it would therefore be covered by paragraph (d)(2) of this section.

(3) A homeless health services grantee makes arrangements with local community providers for after-hours coverage of its patients. The grantee's physicians are required by their employment contracts to provide periodic cross-coverage for patients of these providers, in order to make this arrangement feasible. The Secretary may determine that the arrangement is within the scope of paragraph (d)(3) of this section.

[60 FR 22532, May. 8, 1995; 60 FR 36073, July 13, 1995]

PART 7—DISTRIBUTION OF REFERENCE BIOLOGICAL STANDARDS AND BIOLOGICAL PREPARATIONS

Sec.
7.1 Applicability.
7.2 Establishment of a user charge.
7.3 Definitions.
7.4 Schedule of charges.
7.5 Payment procedures.
7.6 Exemptions.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); title V of the Independent Offices Appropriation Act of 1952 (31 U.S.C. 9701); and sec. 352 of the Public Health Service Act, as amended (42 U.S.C. 263).

SOURCE: 52 FR 11073, Apr. 7, 1987, unless otherwise noted.

§ 7.1 Applicability.

The provisions of this part are applicable to private entities requesting from the Centers for Disease Control (CDC) reference biological standards and biological preparations for use in their laboratories.

§ 7.2 Establishment of a user charge.

Except as otherwise provided in §7.6, a user charge shall be imposed to cover the cost to CDC of producing and distributing reference biological standards and biological preparations.

§ 7.3 Definitions.

Biological standards means a uniform and stable reference biological substance which allows measurements of relative potency to be made and described in a common currency of international and national units of activity.

Biological preparations means a reference biological substance which may be used for a purpose similar to that of a standard, but which has been established without a full collaborative study, or where a collaborative study has shown that it is not appropriate to establish the preparation as an international standard.

§ 7.4 Schedule of charges.

The charges imposed in §7.2 are based on the amount published in CDC's price list of available products. These charges will reflect direct costs (such as salaries and equipment), indirect costs (such as rent, telephone service, and a proportionate share of management and administrative costs), and the costs of particular ingredients. Charges may vary over time and between different biological standards or biological preparations, depending upon the cost of ingredients and the complexity of production. An up-to-date schedule of charges is available from the Biological Products Branch, Center for Infectious Diseases, Centers for Disease Control, 1600 Clifton Road, Atlanta, Georgia 30333.

§ 7.5 Payment procedures.

The requester may obtain information on terms of payment and a fee schedule by writing the ''Centers for Disease Control,'' Financial Management Office, Buckhead Facility, Room 200, Centers for Disease Control, 1600 Clifton Road, Atlanta, Georgia 30333.

§ 7.6 Exemptions.

State and local health departments, governmental institutions (e.g., State hospitals and universities), the World Health Organization, and ministries of health of foreign governments may be exempted from paying user charges, when using biological standards or biological preparations for public health purposes.